University of Basel

Institute for
Biomedical Ethics

The notion of data donation: conceptual explanations, implementations and relevance for Swiss health data governance

On behalf of

Federal Office of Public Health FOPH, Switzerland

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Executive summaries

Deutsch

Die größte Herausforderung bei der Data Governance im biomedizinischen Bereich besteht heute darin, ein Gleichgewicht zwischen dem Schutz der Privatsphäre des Einzelnen und der Erleichterung des Datenflusses zwischen Gesundheitswesen und Forschung herzustellen. In der politischen Debatte wird häufig argumentiert, dass das Konzept der Datenspende dazu beitragen könnte. Der genaue Inhalt dieses Konzepts und seine Auswirkungen auf die Data Governance sind jedoch nicht klar. Der Zweck des vorliegenden Berichts ist es, diese Fragen zu untersuchen. Seine genauen Ziele sind:

1) Zu verstehen, was unter das Konzept der Datenspende in Bezug auf die sekundäre Nutzung von Daten für die biomedizinische Forschung fällt;
2) Zu ermitteln, welche konkreten und möglichen Interpretationen und Umsetzungen des Konzepts existieren. Diese Ziele werden auch in der Absicht verfolgt, Empfehlungen für die zukünftige Entwicklung der Data Governance in der Schweiz abzuleiten.

Kapitel 2 gibt zunächst einen Überblick über den Ursprung, die Entwicklung und die Merkmale des Konzepts der Datenspende. Der Begriff wurde erstmals in den 2000er Jahren im akademischen Kontext erwähnt, um vorzuschlagen, dass es Einzelpersonen erlaubt sein sollte, bestimmte Gesundheitsdaten für die Forschung zu spenden, so wie es auch mit Organen möglich ist. Dieses ursprüngliche Konzept wurde - immer noch im akademischen Kontext als rein hypothetischer Vorschlag - in den 2010er Jahren weiterentwickelt. Weitere Wissenschaftler aus den Bereichen Bioethik, biomedizinische Forschung und Gesundheitspolitik begannen, die Idee zu bekräftigen, dass es eine Regelung geben sollte, die Datenspenden nach dem Tod ermöglicht. In der Praxis bestand der Vorschlag darin, Regelungen zu schaffen, die es den Bürgern erlauben würden, eindeutig zu erklären, dass ihre zuvor gesammelten Gesundheitsdaten nach ihrem Tod für die Forschung weiterverwendet werden dürfen. Ziel war es, diese Art der Weiterverwendung von Daten für die Forschung im öffentlichen Interesse zu erleichtern, die ansonsten von ethischer und rechtlicher Unsicherheit geprägt war. Dies wurde als dringende ethische Notwendigkeit beschrieben, da die posthume Wiederverwendung von Daten für die Forschung kaum Risiken für die Privatsphäre mit sich bringt und daher erleichtert werden sollte. Es wurde zudem argumentiert, dass die Datenspende auch zu Lebzeiten erlaubt sein sollte, d.h. dass Einzelpersonen zu jedem Zeitpunkt ihres Lebens die Möglichkeit haben sollten, Daten für Forschungszwecke im öffentlichen Interesse oder für das Gemeinwohl zu spenden. Dieser Vorschlag zur Schaffung von Datenspendesystemen war jedoch mit Unsicherheiten behaftet: Wie kann der Begriff "Spende" auf Daten angewandt werden, die - anders als bei der Organspende - immaterielle Objekte sind? Wie lässt sich dies mit den bestehenden Regeln für die Weiterverwendung von Daten kombinieren (z.B. spezifische informierte Einwilligung oder breite Einwilligung)? Wie kann es von einem rein akademischen Vorschlag zu einer konkreten politischen Umsetzung kommen?

Die Debatte über diese Aspekte wurde in zwei Kontexten weitergeführt. Zum einen im Rahmen einer Zusammenarbeit zwischen Microsoft und der Universität Oxford. Dies führte

zu mehreren Veröffentlichungen über die Datenspende, in denen versucht wurde, die Bedeutung des Konzepts besser zu definieren und Vorschläge zu seiner Umsetzung zu machen. Dabei wurde betont, dass mit der Datenspende nur der Fall der posthumen Weiterverwendung von Daten für die Forschung geregelt werden sollte und nur die Weiterverwendung von Daten im öffentlichen Interesse ermöglichen sollte. Zweitens, im Rahmen der COVID-19-Pandemie, als viele Forschungs- und Politikinitiativen, die Gesundheitsdaten für Zwecke der öffentlichen Gesundheit benötigten, begannen zu Datenspenden von Einzelpersonen aufzurufen. Sie wollten auch unterstreichen, dass die Bereitstellung von Daten für solche gemeinnützigen Zwecke fast einer moralischen Pflicht gleichkommt.

Trotz der Fortschritte in der Debatte über das Konzept der Datenspende ist dieses Thema nach wie vor durch viele Unklarheiten gekennzeichnet. Die wichtigsten davon sind:

1) Das Fehlen einer einheitlichen Definition des Begriffs Datenspende;
2) Unterschiedliche Auffassungen darüber, ob der Begriff nur für die posthume Weiterverwendung von Daten oder auch für die Weiterverwendung von Daten lebender Personen verwendet werden sollte;
3) Die Beziehung zwischen Datenspende und Einwilligung;
4) Obwohl Einigkeit darüber besteht, dass die Datenspende für die Weiterverwendung von Daten im öffentlichen Interesse oder für das Gemeinwohl eingesetzt werden sollte, herrscht Uneinigkeit darüber, wie diese Begriffe zu definieren sind.

Ein Grund für die Unklarheiten über das Konzept der Datenspende ist auch, dass die Grenzen zu anderen verwandten Konzepten der Data Governance unscharf sind. In der Tat wurden in letzter Zeit viele andere Konzepte entwickelt, um die Idee zu unterstreichen, dass die Weiterverwendung von Daten für das Gemeinwohl erleichtert werden sollte, darunter: Datenphilanthropie, Datenaltruismus, Datensolidarität. Darüber hinaus ist die Abgrenzung zu resp. die Beziehung zwischen Datenspende und verschiedenen Modellen der Einwilligung (spezifische informierte Einwilligung, dynamische Einwilligung, meta-Einwilligung, wertbasierte Einwilligung, breite Einwilligung und Generalkonsent) nicht ganz klar.

Ausgehend von der Entwicklung der Debatte scheinen für das Konzept der Datenspende jedoch folgende Tatsachen charakteristisch zu sein:

1) das Konzept bzw. der Begriff Datenspende sollte nur für die Weiterverwendung von Daten im öffentlichen Interesse oder zum Wohle der Allgemeinheit und nicht für jede Art von Sekundärnutzung angewendet werden;
2) eine gewisse Kontrolle durch Einzelpersonen (z.B. die Möglichkeit, die Datenspende zu bestätigen oder ihr zu widersprechen) sollte ein Merkmal der Umsetzung des Konzeptes sein.

Kapitel 3 zeigt im Überblick verschiedene politische Massnahmen im internationalen Kontext, um zu verdeutlichen, wie sich die Umsetzung der Datenspende oder verwandter Konzepte präsentieren kann. Zu Beginn des Kapitels wird jedoch eine wichtige Unterscheidung hervorgehoben. Die Datenspende kann als rechtliches Konzept umgesetzt werden, d.h. es werden rechtliche Regelungen geschaffen, die definieren, was dies ist und wie es funktioniert. Sie kann aber auch als symbolisches Konzept umgesetzt werden, d.h. politische oder Forschungsinitiativen können die Sammlung und Weiterverwendung von

Daten als "Spenden" bezeichnen, auch wenn diese weiterhin auf anderen Rechtsgrundlagen (z.B. Einwilligung) beruhen.

Was die internationalen Beispiele für die Umsetzung von der Datenspende oder verwandten Konzepten angeht, so werden mehrere Kontexte beschrieben.
In England hat das Nationale Gesundheitssystem (NHS) eine Reihe von Diensten für die Verwaltung und Weiterverwendung der von ihm gesammelten Gesundheitsdaten entwickelt, die einzelne Merkmale der Datenspende aufweisen. In der Tat können NHS-Daten für Forschungszwecke im öffentlichen Interesse weiterverwendet werden, aber Einzelpersonen haben die Möglichkeit, dies über das National Data Opt Out Register abzulehnen.
In den Niederlanden gab es einen Vorschlag zur Schaffung von Donata, einer Plattform, auf der Einzelpersonen bestimmte Daten für die Forschung im öffentlichen Interesse spenden können, je nachdem, was Forscher an spezifischen medizinischen Informationen benötigen. Es gibt jedoch keine öffentlich zugänglichen Informationen darüber, ob der Vorschlag tatsächlich umgesetzt wurde.
In Dänemark und Finnland werden eine große Menge an Gesundheitsdaten automatisch in den nationalen Gesundheitssystemen erfasst und für die Forschung gemäß einem Data-Governance-Modell weiterverwendet, das dem Konzept der Datensolidarität ähneln soll. Beide Länder haben zentralisierte öffentliche Gesundheitsdatenagenturen, die die Genehmigungen für externe Forscher zur Weiterverwendung einiger nationaler Gesundheitsdaten verwalten, solange die Forschung nachweisen kann, dass dies im öffentlichen Interesse liegt.
In Frankreich wurde kürzlich der Health Data Hub gegründet, um die Idee der Datenspende symbolisch zu erleichtern. Diese Agentur verwaltet und/oder koordiniert die Weiterverwendung von Gesundheitsdaten aus einer Reihe von wichtigen Gesundheitsdatenbanken und verfügt ausserdem über ein Verfahren, das die Förderung von Sekundärforschungsprojekten im öffentlichen Interesse sicherstellt.
Deutschland ist ein weiteres Land, in dem das Konzept der Datenspende schon seit einiger Zeit in der politischen Debatte eine Rolle spielt. Es gibt einige aktuelle Gesetzesänderungen, die versuchen, ein System zu implementieren, bei dem Krankenversicherungsdaten und/oder Daten in der elektronischen Patientenakte für die Forschung im öffentlichen Interesse weiterverwendet werden können, wobei dem Einzelnen einige Rechte (z.B. das Recht auf Opt-out) verbleiben. Eine spezielle Agentur, die einige der regulatorischen Aspekte in dieser Hinsicht verwaltet, ist ebenfalls vorgesehen.
Schließlich hat die Europäische Union ein Gesetz (Daten-Governance-Rechtsakt) verabschiedet, das das rechtliche Konzept des Datenaltruismus operationalisiert. Dieses Gesetz sieht die Schaffung von Daten-Altruismus-Organisationen in den EU-Mitgliedsstaaten vor, denen Einzelpersonen durch eine spezielle Daten-Altruismus-Einwilligungserklärung Daten spenden können und die dann Zugang zur (inter)nationalen Weiterverwendung dieser Daten für gemeinnützige Zwecke gewähren können. Bisher wurde in der gesamten EU jedoch nur eine solche Organisation gegründet. Die jüngste Umsetzung der Verordnung über den europäischen Raum für Gesundheitsdaten auf EU-Ebene wird diese Entwicklungen beeinflussen.

Kapitel 4 befasst sich mit dem Thema der Datenspende im Schweizer Kontext. Zu Beginn wird dargestellt, dass es einige Pionierinitiativen gab, die versuchten, die Datenspende auch in der Schweiz symbolisch umzusetzen.

Die erste war ein Projekt der Stiftung Risiko-Dialog, die zwei Use-Cases für die Implementierung von Daten als symbolisches Konzept entwickelte. Ein Use-Case war eine Zusammenarbeit mit der Universität Zürich, um mit einem Fragebogen während der COVID-19-Pandemie zu untersuchen, ob Mitarbeitende der Universität bereit wären, Daten für Sekundärnutzung zu einem nichtkommerziellen Zweck (z.B. Bekämpfung der Pandemie) zur Verfügung zu stellen und dies als Datenspende zu formulieren. Viele antworteten positiv, aber die Studie ergab auch, dass - wenn es darum ging, die Daten wirklich zu spenden/zur Verfügung zu stellen - nur ein kleiner Teil dies tat. Dies zeigt, dass die Bereitschaft zu spenden nicht bedeutet, dass die Leute dann auch tatsächlich Daten spenden werden. Der zweite Anwendungsfall war eine Zusammenarbeit mit der Stadt Zürich und betraf die Sammlung und Weiterverwendung von Mobilitätsdaten für die Forschung im öffentlichen Interesse, einschliesslich Klima und öffentliche Gesundheit. Es wurde eine Kampagne gestartet, um die Bürger zu ermutigen, Mobilitätsdaten für eine sekundäre Nutzung zur Verfügung zu stellen, und die Bereitstellung der Daten wurde symbolisch als Spende dargestellt. Die Daten wurden über eine speziell entwickelte App gesammelt und die Menschen ergänzend befragt, was sie motiviert ihre Daten zu spenden (z.B. die Tatsache, dass die Daten für das öffentliche Interesse wiederverwendet werden).

Eine weitere Schweizer Initiative ist das Data Donation Lab an der Universität Zürich. Es wurde als Wissenszentrum für Forschungsinitiativen gegründet, die das Sammeln von Daten von Forschungsteilnehmenden und deren Weiterverwendung als "Datenspende" im symbolischen Sinne verstehen.

Die Gemeinsamkeiten der beschriebenen Initiativen zur Umsetzung von Datenspenden in der Schweiz sind:

1) Dass sie die Datenspende als symbolisches Konzept verstehen;
2) Dass ihr Hauptmerkmal in ihrer Umsetzung die Bereitstellung von Daten für Projekte/Ziele von allgemeinem/öffentlichem Interesse ist;
3) Dass Einzelpersonen als Katalysatoren der von ihnen gesammelten Daten im Mittelpunkt stehen, auch in dem Sinne, dass ihre Handlungen der Datenspende bewusst und explizit sein müssen (keine Opt-Out Lösung, wo die Spende automatisch ist);
4) Dass sie sich auf bestimmte Datensätze und deren Wiederverwendung konzentrieren und nicht auf Gesundheitsdaten im Allgemeinen;
5) Dass sie keine posthume Datenspende in Betracht ziehen.

Abgesehen von diesen Initiativen, die sich explizit um die Umsetzung der Datenspende bemühen, gab es in der Schweiz in letzter Zeit mehrere andere relevante politische Entwicklungen zur Weiterwendung von Daten für die Forschung. So wurde beispielsweise das elektronische Patientendossier weiter umgesetzt, und eine Gesetzesänderung, die es Nutzern ermöglichen würde, der Weiterverwendung ihrer Daten für die Forschung zuzustimmen, wird derzeit geprüft. Darüber hinaus verfügen die kantonalen Krebsregister nun über einen spezifischen Rechtsrahmen, der es ihnen ermöglicht, Daten automatisch zu sammeln (und dann weiterzuverwenden), wobei die Betroffenen lediglich das Recht haben, sich dagegen zu entscheiden. Ein überarbeitetes Bundesgesetz über den Datenschutz wurde ebenfalls vor kurzem verabschiedet, und die Humanforschungsverordnung wird derzeit überarbeitet, um die Erteilung der Einwilligung in elektronischer Form zu ermöglichen. Ausserdem wurde die Schaffung eines neuen allgemeinen Rahmengesetzes für die Sekundärnutzung von Daten präsentiert. Schließlich haben auch Initiativen wie das Swiss Personalized Health Network und der Versuch, die Generalkonsente der Universitätskliniken zu harmonisieren, Auswirkungen auf die nationale Verwaltung von Gesundheitsdaten.

In Bezug auf die Schweiz wird zuletzt ein Überblick gegeben über die bisher durchgeführte Forschung zur Bereitschaft der Bevölkerung, Daten für eine Sekundärnutzung zu teilen, auch in Form einer Datenspende. Es wurde eine Reihe von Studien durchgeführt, die sowohl quantitativ (nationale Umfragen) als auch qualitativ (auf der Basis von Interviews) angelegt waren. Zusammengefasst zeigte sich:

1) Studien untersuchen nicht notwendigerweise das Konzept der "Datenspende", sondern eher die allgemeine Bereitschaft, Daten für Sekundärforschungszwecke zur Verfügung zu stellen;
2) Die Mehrheit der Bevölkerung steht der Idee, Daten für Sekundärforschungszwecke zur Verfügung zu stellen, im Allgemeinen positiv gegenüber, aber:
    a. Die Erklärung der Absicht, Daten zu teilen, entspricht nicht der tatsächlichen Weitergabe von Daten und
    b. Einzelpersonen knüpfen ihre Einstellung zur Weitergabe von Daten häufig an Bedingungen (z. B. abhängig davon, wer sie aufbewahrt und/oder Zugang zu ihnen für die Sekundärnutzung hat);
3) Die Studien zeigten auch ein geringes Verständnis bestimmter Themen (z.B. Anonymisierung vs. Pseudonymisierung) und den Wunsch, besser darüber informiert zu werden, welche Sekundärnutzung genau mit den Daten betrieben wird.

Kapitel 5 enthält einige abschließende Überlegungen zu den potenziellen Auswirkungen der Datenspende, wenn sie in der Schweizer Politik zur Health Data Governance weiter umgesetzt wird. Zunächst muss eingeräumt werden, dass das Konzept der Datenspende nach wie vor mit vielen Unsicherheiten behaftet ist, die eine Umsetzung im Schweizer Kontext erschweren. Gleichzeitig ist klar, dass ein besonderes Merkmal der Datenspende darin besteht, dass sie darauf abzielt, die Sekundärnutzung von Daten im öffentlichen Interesse oder zum Wohle der Allgemeinheit zu regeln. Dieser forschungsfreundliche Ansatz würde gut zu der jüngsten Entwicklung vieler Teile des schweizerischen Gesundheitsdatenraums passen, einschließlich des elektronischen Patientendossiers und der kantonalen Krebsregister. Daher könnte die Einführung der Datenspende diese Bemühungen unterstützen und einige der rechtlichen Unsicherheiten klären, die bei der Weiterverwendung von sicherheitsrelevanten Daten aus unterschiedlichen Datenbanken noch bestehen.

Die Umsetzung der Datenspende in der Schweiz würde den politischen Entscheidungsträgern eine Reihe von Entscheidungen abverlangen. Erstens müssten sie entscheiden, ob es sich um ein rechtliches oder ein symbolisches Konzept handeln soll. Zweitens müsste festgelegt werden, ob sie nur für die posthume Weiterverwendung von Daten oder auch für die Weiterverwendung von Daten lebender Personen gelten soll. Jede dieser Optionen hat mehrere Vor- und Nachteile. Insgesamt scheint eine gesetzliche Umsetzung vorzuziehen zu sein, da sie mehr Rechtssicherheit bietet und eine Irreführung des Einzelnen verhindert. Darüber hinaus hätte eine Umsetzung sowohl für die in-vivo als auch für die posthume Weiterverwendung von Daten den Vorteil, dass es ein einheitliches Regulierungssystem für die Sekundärnutzung für Planung, Steuerung und Forschung im öffentlichen Interesse gäbe. In diesem Fall könnte eine potenzielle Nationale Datenkoordinationsstelle eine zentrale Rolle spielen. Sie könnte unter anderem beurteilen, welche Sekundärnutzung dem öffentlichen Interesse entspricht und unter welchen Bedingungen individuelle Rechte ausgeübt werden können (z.B. das Recht, Daten von der Weiterverwendung auszuschliessen). Darüber hinaus könnte die Koordinationsstelle dazu beitragen, die Vermittlung zwischen den verschiedenen Akteuren des Gesundheitsdatenraums zu erleichtern und ein breites öffentliches Engagement für das Verständnis der Gesamtstruktur der Data Governance sicherzustellen. Schließlich müsste jede Umsetzung der Datenspende: 1) sicherstellen, dass Lehren aus anderen Ländern, die ebenfalls ihren Gesundheitsdatenraum (mit Infrastrukturen, Dienstleistungen und Rechtsrahmen)entwickeln, berücksichtigt werden; 2) das Zusammenspiel zwischen der Datenspende und anderen bestehenden Konzepten der Health Data Governance (z.B. Generalkonsent) geklärt werden.

Eine wichtige Aufgabe für die Zukunft besteht auch darin, zu beobachten, wie sich die Einstellung der Öffentlichkeit zur Bereitstellung von Daten für sekundäre Nutzungszwecke entwickelt. Die vorliegenden Studien zeigen, dass die Bereitschaft, Daten für die Forschung zu spenden, im Allgemeinen positiv ist, dass aber auch viele Bedenken bestehen, insbesondere in Abhängigkeit davon, wer die Daten weiterverwendet. Darüber hinaus gibt es eine Wissenslücke hinsichtlich der Einstellung zur posthumen Datenspende. Es besteht auch die Notwendigkeit, das Niveau der digitalen Gesundheitskompetenz der Bevölkerung zu untersuchen, da es anscheinend Verwirrung über die Bedeutung von Begriffen bzw. von Verfahren zur De-Identifizierung von individuellen Datensätzen gibt. Schliesslich sollten zukünftige Studien auch klären, ob es kulturelle Unterschiede in der Einstellung zur Datenspende gibt und insbesondere nicht nur die Bereitschaft, sondern die tatsächliche Veranlagung zur Spende untersuchen. Letzteres kann durch die Durchführung von Studien geschehen, die das Risiko einer Verzerrung durch das Social-Desirability Bias verringern.

Français

En matière de réglementation de la gouvernance des données dans le domaine biomédical, le principal défi contemporain consiste à trouver un équilibre entre la protection de la vie privée des individus et la promotion du flux de données entre les soins de santé et la recherche. Dans le débat politique récent, on avance souvent que le concept de don de données pourrait aider à trouver cet équilibre. Toutefois, le contenu exact de ce concept et ses implications en matière de gouvernance ne sont pas clairs. L'objectif de ce rapport est d'examiner ces questions. Ses objectifs précis sont :

1) Aider à comprendre ce que recouvre le concept de don de données en ce qui concerne l'utilisation secondaire des données pour la recherche biomédicale ;
2) Identifier les interprétations et les mises en œuvre concrètes et potentielles de ce concept. Ces objectifs sont également poursuivis dans l’intention de formuler des recommandations pour l'évolution future de la gouvernance des données en Suisse.

Le chapitre 2 commence par donner un aperçu de l'origine, des évolutions et des caractéristiques du concept de don de données. Le terme a été mentionné pour la première fois au début des années 2000 dans un contexte académique, pour suggérer que les individus devraient être autorisés à donner certaines données de santé pour la recherche, tout comme il est possible de le faire avec des organes. Cette conception initiale a été davantage développée - toujours dans un contexte académique en tant que proposition purement hypothétique - dans les années 2010. De plus en plus d'universitaires issus des disciplines de la bioéthique, de la recherche biomédicale et de la politique de santé ont commencé à renforcer l'idée qu'une réglementation devrait être mise en place pour permettre les dons de données après la mort. En pratique, la proposition consistait à suggérer la création de réglementations permettant aux citoyens d'indiquer clairement que leurs données de santé précédemment collectées pourraient être réutilisées pour la recherche, même après leur décès. L'objectif était de faciliter ce type de réutilisation des données pour la recherche d'intérêt public, qui était autrement entourée d'incertitude éthico-légale. Cette mesure a été décrite comme une nécessité éthique urgente, car la réutilisation posthume de données à des fins de recherche pose peu de risques pour la vie privée et devrait donc être facilitée. Certains commentateurs ont commencé à soutenir que le don de données devrait également être autorisé de son vivant, c’est-à-dire que les individus devraient aussi pouvoir donner leurs données à des fins de recherche dans l'intérêt public ou pour le bien commun à tout moment de leur vie. Cette proposition de création de systèmes de don de données était toutefois truffée d'incertitudes : comment l'idée de "don" peut-elle s'appliquer aux données, qui sont - contrairement aux organes - des objets intangibles ? Comment combiner cette idée avec les règles existantes en matière de réutilisation des données (par exemple, le consentement éclairé spécifique ou général) ? Comment passer d'une proposition purement académique à une mise en œuvre politique concrète ?

Le débat sur ces aspects a été soulevé dans deux contextes. Premièrement, grâce à une collaboration entre Microsoft et l'Université d'Oxford. Cela a donné lieu à plusieurs publications sur le don de données, visant à mieux définir le concept et à proposer des pistes pour sa mise en œuvre. L'accent a été mis sur le fait que le don de données devrait servir uniquement à encadrer la réutilisation posthume des données à des fins de recherche, et qu'il ne devrait faciliter leur réutilisation que dans l'intérêt public. Deuxièmement, la pandémie de COVID-19 a mis en lumière de nombreuses initiatives de recherche et de politique nécessitant des données de santé à des fins de santé publique, incitant à appeler au don de données de la part de particuliers et soulignant que fournir des données pour de telles causes de bien commun revient presque à un devoir moral.

Malgré les avancées dans le débat sur le concept de don de données, de nombreuses incertitudes persistent et caractérisent ce sujet. Les principales sont les suivantes :

1) L'absence d'une définition uniforme du concept de don de données ;
2) Les divergences d'opinions quant à son application uniquement pour la réutilisation posthume des données ou également pour la réutilisation des données de personnes vivantes ;
3) La relation entre le don de données et le consentement ;
4) Bien qu'il soit généralement accepté que le don de données devrait être mis en œuvre pour la réutilisation de données dans l'intérêt public ou pour le bien commun, il existe des désaccords sur la manière de définir ces concepts.

L'une des raisons des incertitudes entourant le concept de don de données réside également dans le fait que ses frontières avec d'autres concepts liés à la gouvernance des données ne sont pas clairement définies. En effet, récemment, de nombreux autres concepts ont été développés pour souligner l'idée que la réutilisation des données à des fins de bien public devrait être facilitée, notamment : la philanthropie de données, l'altruisme de données, et la solidarité de données. De plus, la délimitation ou la relation entre le don de données et plusieurs modèles de consentement (spécifique, dynamique, méta, basé sur les valeurs la valeurs, large et général) n'est pas totalement claire.
Sur la base de l'évolution du débat, les éléments suivants semblent toutefois caractériser le concept de don de données :

1) Le concept ou le terme "don de données" ne devrait faire référence qu'à la réutilisation de données dans l'intérêt public ou au profit de la communauté, et non à une quelconque utilisation secondaire ;
2) Un certain degré de contrôle par les individus (par exemple, la possibilité de confirmer ou de s'opposer au don de données) doit être une caractéristique fondamentale de la mise en œuvre du concept.

Le chapitre 3 donne un aperçu de diverses mesures politiques dans le contexte international afin d'illustrer la manière dont le don de données ou les concepts connexes peuvent être mis en œuvre. Cependant, le chapitre commence par mettre en avant une distinction essentielle. Le don de données peut être mis en œuvre en tant que concept légal, ce qui signifie que des règles légales sont établies pour définir ce qu'est le don de données et comment il fonctionne. Il peut également être mis en œuvre en tant que concept symbolique, où des initiatives politiques ou de recherche peuvent présenter la collecte et la réutilisation des données comme des "actes de don", même si ceux-ci reposent sur d'autres bases légales (par exemple, le consentement).

En ce qui concerne les exemples internationaux de mise en œuvre du don de données ou de concepts connexes, plusieurs contextes sont décrits.
En Angleterre, le National Health Service (NHS) a développé une série de services pour la gestion et la réutilisation des données de santé qu'il collecte, qui présente des similitudes

avec le don de données. En effet, les données du NHS peuvent être réutilisées à des fins de recherche d'intérêt public, mais les individus peuvent choisir de s'y opposer via le registre national de refus des données (National Data Opt Out register).
Aux Pays-Bas, il y a eu une proposition de créer Donata, une plateforme où les individus pourraient faire don de certaines données pour la recherche d'intérêt public, en fonction des besoins des chercheurs en termes d'informations médicales précises. Cependant, il n’y pas d’information publiquement disponible sur la mise en œuvre effective de cette proposition.
Au Danemark et en Finlande, une grande quantité de données de santé est collectée automatiquement dans leurs systèmes nationaux de santé et peut être réutilisée à des fins de recherche selon un modèle de gouvernance des données qui ressemble au concept de solidarité de données. Ils disposent tous deux d'agences centrales de données de santé publique, qui gèrent les autorisations accordées aux chercheurs externes pour la réutilisation de certaines données nationales de santé, à condition que la recherche puisse démontrer son lien avec l'intérêt public.
En France, le Health Data Hub a été récemment créé dans l’optique de symboliser le concept de don de données. Cette agence gère et/ou coordonne la réutilisation des données de santé issues d'une série de bases de données importantes, tout en mettant en place une procédure pour promouvoir les projets de recherche secondaire dans l'intérêt public.
L'Allemagne est un autre pays où le concept de don de données est au cœur du débat politique depuis un certain temps. Des changements réglementaires récents (et en cours d'élaboration) visent à établir un système permettant la réutilisation des données de l'assurance maladie et/ou les données du dossier électronique du patient à des fins de recherche d’intérêt public, tout en préservant certains droits (par exemple, le droit d’opposition) pour les individus. La création d’une agence spéciale chargée de gérer certains aspects réglementaires à cet égard est également envisagée.
Enfin, l'Union européenne a adopté une loi (Règlement sur la gouvernance des données) opérationnalisant le concept légal d'altruisme de données. Cette loi prévoit la création d'organisations d'altruisme de données dans les États membres de l'UE, auxquelles les individus peuvent faire don de leurs données via un formulaire de consentement spécifique à l'altruisme de données, et qui peuvent ensuite accorder l'accès à la réutilisation (inter)nationale de ces données à des fins non lucratives. Jusqu'à présent, une seule de ces organisations a été créée dans toute l'UE. La récente mise en œuvre du règlement relatif à l’espace européen des données de santé niveau de l'UE devrait avoir une influence sur ces développements.

Le chapitre 4 se focalise sur le don de données dans le contexte suisse. Il commence par présenter quelques initiatives pionnières visant à mettre en œuvre de manière symbolique le don de données en Suisse également.
La première de ces initiatives était un projet de la fondation Risiko-Dialog, qui a développé deux cas d'utilisation pour la mise en œuvre du don de données en tant que concept symbolique. L'un de ces cas concernait une collaboration avec l'Université de Zürich pour étudier, à l'aide d'un questionnaire pendant la pandémie de COVID-19, la disposition des employés de l'Université à fournir des données pour la recherche secondaire à des fins non commerciales (par exemple, la lutte contre la pandémie), en définissant cela comme un don de données. Bien que beaucoup aient répondu positivement, l'étude a également révélé qu’une petite partie seulement a effectivement donné leurs données, lorsque cela a

été requis. Cela démontre que la volonté de faire un don ne se traduit pas nécessairement par une action concrète de don. Le deuxième cas d'utilisation concernait une collaboration avec la ville de Zurich portant sur la collecte et la réutilisation des données de mobilité pour la recherche d'intérêt public, notamment pour le climat et la santé publique. Une campagne a été lancée pour encourager les individus à fournir des données de mobilité pour une utilisation secondaire, présentant symboliquement cet acte comme un don. Les données ont été collectées via une application spécialement conçue à cet effet, accompagnée de questionnaires visant à comprendre ce qui motivait les participants à donner leurs données (par exemple, le fait que les données seraient réutilisées dans l'intérêt public).

Une autre initiative suisse est le Data Donation Lab de l'Université de Zurich. Ce laboratoire a été récemment créé pour devenir un centre de connaissances pour les initiatives de recherche encadrant la collecte de données auprès des participants et leur réutilisation en tant qu’ "actes de don de données" dans un sens symbolique.

Les caractéristiques communes de ces initiatives suisses pour la mise en œuvre du don de données sont les suivantes :

1) Elles conçoivent le don de données comme un concept symbolique ;
2) Leur principale caractéristique est l'acte de fournir des données pour des projets/objectifs d'intérêt général/public ;
3) Elles placent les individus au centre, en tant que catalyseurs des données qu'ils collectent, nécessitant des actes de don de données conscients et explicites (sans possibilité d'opt-out) ;
4) Elles se concentrent sur des ensembles spécifiques de données et leur réutilisation, plutôt que sur les données de santé en général ; et
5) Elles n'envisagent pas le don de données à titre posthume.

Outre ces initiatives qui tentent explicitement de mettre en œuvre le don de données, plusieurs autres changements politiques pertinents ont récemment eu lieu en Suisse concernant la réutilisation des données à des fins de recherche. Par exemple, la mise en œuvre du dossier électronique du patient s'est poursuivie et une modification de la loi permettant aux utilisateurs de consentir à la réutilisation de leurs données à des fins de recherche est actuellement examinée. De plus, les registres cantonaux du cancer disposent désormais d'un cadre légal spécifique leur permettant de collecter (puis de réutiliser) automatiquement des données, les individus ayant seulement le droit de s’y opposer. Une loi fédérale révisée sur la protection des données a également récemment été adoptée, et l'Ordonnance sur la recherche sur l'être humain est actuellement en cours de révision pour permettre l'obtention du consentement sous forme électronique. En outre, la création d'une nouvelle loi-cadre générale sur l'utilisation secondaire des données a été proposée. Enfin, des initiatives telles que le Réseau suisse de santé personnalisée et la tentative d'harmoniser les formulaires de consentement général dans les hôpitaux universitaires ont également un impact sur la gouvernance nationale des données de santé.

En ce qui concerne la Suisse, la dernière partie du chapitre donne un aperçu des études menées à ce jour sur la volonté de la population de partager des données pour une utilisation secondaire, y compris sous la forme d'un don de données. Un certain nombre d'études ont été menées, combinant à la fois des approches quantitatives (enquêtes nationales) et qualitatives (entretiens). En résumé, il est apparu que :

1) Les études n’abordent généralement pas sur le concept de "don de données", mais plutôt sur la volonté générale des individus de fournir leurs données à des fins de recherche secondaire ;
2) En règle générale, la majorité de la population a une attitude positive à l'égard de fournir leurs données à des fins de recherche secondaire. Cependant,
    a. Déclarer l'intention de partager des données ne se traduit pas toujours par un partage effectif et
    b. Les individus posent souvent des conditions à leur volonté de partager des données (par exemple, en fonction de la gestion et l’accès aux données pour l’utilisation secondaire) ;
3) Les études indiquent également une compréhension limitée de certaines questions (par exemple, l'anonymisation par rapport à la pseudonymisation) et un désir d'être mieux informé sur la nature exacte de l’utilisation secondaire effectuée avec leurs données.

Le chapitre 5 propose quelques réflexions finales sur l'impact potentiel du don de données, s'il était davantage intégré dans la politique suisse de gouvernance des données de santé. Tout d'abord, il est admis que le concept de don de données demeure entouré d'une grande incertitude, ce qui rendrait sa mise en œuvre dans le contexte suisse difficile. Cependant, il est également clair qu’une caractéristique distinctive du don de données est qu'il vise à réguler l'utilisation secondaire des données pour l'intérêt public ou le bien commun. Cette approche favorable à la recherche correspondrait bien à l'évolution récente de nombreux éléments du cadre suisse des données de santé, notamment le dossier électronique du patient et les registres cantonaux du cancer. Par conséquent, une implémentation du don de données pourrait soutenir ces initiatives et clarifier certaines des incertitudes légales qui subsistent concernant la réutilisation des données provenant des bases de données différentes.

L’implémentation du don de données en Suisse nécessiterait que les décideurs politiques fassent une série de choix. Tout d'abord, il leur faudrait décider s’il convient de le mettre en place en tant que concept légal ou symbolique. Deuxièmement, il serait nécessaire de déterminer si cela devrait s’appliquer uniquement à la réutilisation posthume de données ou également à celle des données de personnes vivantes. Chacune de ces options présente plusieurs avantages et inconvénients. Dans l'ensemble, une implémentation légale semble préférable, car elle offre une plus grande certitude légale et évitant toute confusion pour les individus. En outre, si elle est mise en œuvre à la fois pour la réutilisation des données in vivo et posthumes, l'avantage serait de disposer d'un système réglementaire cohérent pour l’utilisation secondaire pour la planification, le guidage et la recherche d'intérêt public. Dans ce cadre, un éventuel Centre National de Coordination des Données jouerait un rôle central, notamment en déterminant quelles utilisations secondaires servent l'intérêt public et sous quelles conditions les droits individuels peuvent être exercés (par exemple, le droit d'exclure les données de la réutilisation). De plus, ce centre pourrait faciliter la médiation entre les différents acteurs de l’espace des données de santé et encouragerait une large participation du public dans la compréhension de la structure globale de gouvernance des données. Enfin, toute implémentation du don de données devrait : 1) s’assurer que les enseignements tirés des autres pays développant également leur espace de données de santé (avec infrastructures, services et cadre juridique) soient prises en compte ; 2) clarifier les interactions entre le don de données et les autres concepts existants dans la gouvernance des données de santé (par exemple, le consentement général).

Une tâche importante pour l'avenir consiste également à surveiller l'évolution de l'opinion publique sur la fourniture de données à des fins d'utilisation secondaire. Les études actuelles montrent une attitude généralement positive envers le don de données pour la recherche, mais aussi la présence de nombreuses préoccupations, notamment en fonction de selon qui réutilise les données. De plus, il existe un manque de connaissances sur les attitudes envers le don de données à titre posthume. Il est également nécessaire d'étudier le niveau de connaissance de la population en matière de santé numérique, car il semble y avoir une certaine confusion quant à la signification de termes ou des procédures de dé-identification des enregistrements individuels. Enfin, les recherches futures devraient également examiner s'il existe des différences culturelles dans les attitudes envers le don de données et, surtout investiguer non seulement la volonté, mais aussi la prédisposition réelle à faire un don. Cette dernière pourrait être étudiée en menant des études qui réduisent le risque de social-desirability bias.

Italiano

La principale sfida dei giorni nostri nella regolamentazione della governance dei dati nel settore biomedico è quella di trovare un equilibrio tra la protezione della privacy individuale e la facilitazione del flusso di dati tra il sistema sanitario e ricerca. Nel dibattito socio-politico, si sostiene spesso che il concetto di donazione di dati potrebbe essere utilizzato per aiutare a raggiungere questo equilibrio. Tuttavia, il significato esatto di questo concetto e le sue implicazioni per la governance dei dati non sono chiare. L'obiettivo di questo rapporto è quello di analizzare questi temi. I suoi obiettivi precisi sono:

1) Aiutare a capire cosa rientra nel concetto di donazione di dati in relazione all'uso secondario dei dati per la ricerca biomedica;
2) Identificare quali interpretazioni e implementazioni concrete e potenziali del concetto esistono. Questi obiettivi sono perseguiti anche con l'intento di ricavare raccomandazioni per la futura evoluzione della governance dei dati in Svizzera.

Il Capitolo 2 inizia fornendo una panoramica sull'origine, le evoluzioni e le caratteristiche del concetto di donazione di dati. Il termine è stato menzionato per la prima volta all'inizio degli anni 2000 nel contesto accademico, per suggerire che dovrebbe essere possibile per singole persone di donare alcuni dati sanitari per la ricerca, proprio come è possibile fare con gli organi. Questa concezione iniziale è stata ulteriormente sviluppata - sempre nel contesto accademico e come proposta puramente ipotetica - negli anni seguenti. Altri studiosi provenienti dalle discipline della bioetica, della ricerca biomedica e della politica sanitaria hanno iniziato a riproporre l'idea che dovrebbe essere introdotta una regolamentazione per consentire la donazione di dati postuma. In pratica, la proposta consisteva nel suggerire di creare regole che permettessero ai cittadini di dichiarare chiaramente che i loro dati sanitari raccolti in precedenza potevano essere riutilizzati per la ricerca anche dopo la loro morte. Lo scopo era quello di facilitare questo tipo di riutilizzo dei dati per ricerca di pubblico interesse, per ridurre incertezze dal punto di vista etico-legale. Permettere tale donazione di dati veniva dichiarato una priorità etica, poiché il riutilizzo postumo dei dati per la ricerca presenta pochi rischi per la privacy e dovrebbe quindi essere facilitato. Alcuni studiosi hanno poi iniziato a sostenere che la donazione di dati dovrebbe essere consentita anche durante la vita, vale a dire che gli individui dovrebbero poter donare dati per scopi di ricerca nell'interesse pubblico o per il bene comune in qualsiasi momento della loro vita, e non solo post-morte. Queste proposte di rendere possibile la donazione dei dati per il loro riutilizzo a fini di ricerca sono state tuttavia costellate di incertezze: come si può applicare l'idea di 'donazione' ai dati, che sono - a differenza del caso della donazione di organi - oggetti intangibili? Come si possono combinare concetti tuttora esistenti per il riutilizzo dei dati (ad esempio, il consenso informato specifico o consenso ampio)? Come si può passare da una pura proposta accademica a un'attuazione politica concreta?

Il dibattito su questi temi è stato portato avanti in due contesti. In primo luogo, una collaborazione tra Microsoft e l'Università di Oxford. Tale collaborazione ha facilitato diverse pubblicazioni scientifiche sul concetto di donazione di dati, che cercavano di definire meglio il significato di questo termine e di suggerire come implementarlo. In questa contesto, prevaleva la convinzione che la donazione di dati dovrebbe essere utilizzata per regolamentare solo il riutilizzo postumo dei dati per la ricerca. Si è inoltre insistito che la donazione di dati dovrebbe facilitare solo il loro riutilizzo per iniziative di interesse pubblico.

In secondo luogo, durante la pandemia di COVID-19 molte iniziative di ricerca e politiche che necessitavano di dati sanitari per scopi di salute pubblica hanno iniziato a richiedere donazioni di dati da parte di singoli individui, sottolineando che fornire dati per obiettivi di bene comune equivaleva quasi a un dovere morale.

Nonostante i progressi nel dibattito sul tema della donazione di dati, la presenza di molte incertezze rimane la caratteristica distintiva di questo concetto. Le principali sono:

1) L'assenza di una definizione uniforme del concetto di donazione dei dati;
2) Opinioni divergenti se debba essere utilizzata solo per il riutilizzo di dati postumi, o anche per il riutilizzo di dati di persone viventi;
3) La relazione tra la donazione di dati e il consenso informato;
4) Sebbene ci si trovi d’accordo sul fatto che la donazione di dati debba essere attuata per il riutilizzo di dati nell'interesse pubblico o per il bene comune, c'è disaccordo su come definire questi concetti.

Una causa delle incertezze concettuali riguardanti il concetto di donazione di dati è anche che le esatte differenze tra essa ed altri concetti simili nella governance dei dati non sono chiari. Infatti, recentemente sono stati sviluppati molti altri concetti per sottolineare l'idea che il riutilizzo dei dati per il bene pubblico dovrebbe essere facilitato, tra cui: filantropia dei dati, altruismo dei dati, solidarietà dei dati. Inoltre, la demarcazione o la relazione tra la donazione di dati e diversi modelli di consenso (consenso specifico, consenso dinamico, meta-consenso, consenso valoriale, consenso ampio, e consenso generale) non è esattamente chiara.

In base allo sviluppo del dibattito, tuttavia, i seguenti elementi sembrano caratterizzare il concetto di donazione di dati:

1) il concetto o termine di donazione di dati deve essere riferito solo al riutilizzo dei dati nell'interesse pubblico o a beneficio della collettività e non per qualsiasi tipo di uso secondario;
2) un certo grado di controllo da parte delle persone (ad esempio, la possibilità di confermare o di opporsi alla donazione dei dati) deve essere una caratteristica fondamentale dell'implementazione del concetto.

Il Capitolo 3 offre una panoramica di varie misure politiche nel contesto internazionale, per illustrare come la donazione di dati o i concetti correlati possano essere implementati. Il capitolo inizia tuttavia sottolineando una distinzione chiave. La donazione di dati può essere implementata come concetto legale, il che significa che verrebbero create regole legali che definiscono cosa sia e come funzioni. Tuttavia, può anche essere implementata come concetto simbolico, il che significa che le iniziative politiche o di ricerca potrebbero inquadrare la raccolta e il riutilizzo dei dati come 'atti di donazione', anche se questi rimangono basati su altre basi legali (ad esempio, il consenso informato).

In termini di esempi internazionali di implementazione della donazione di dati o di concetti correlati, vengono descritti diversi contesti.

In Inghilterra, il Sistema Sanitario Nazionale (NHS) ha sviluppato una serie di servizi per la gestione e il riutilizzo dei dati sanitari che esso raccoglie, che nel complesso presentano molte caratteristiche che rimandano alla donazione di dati. Infatti, i dati dell’NHS possono essere riutilizzati per la ricerca nell'interesse pubblico, ma gli individui possono scegliere di non partecipare a questa attività attraverso un registro nazionale di opt-out per i dati sanitari.

Nei Paesi Bassi, è stata avanzata la proposta di creare Donata, una piattaforma in cui gli individui possono donare determinati dati per la ricerca di pubblico interesse, in base alle esigenze dei ricercatori in termini di informazioni mediche specifiche di cui hanno bisogno. Tuttavia, non ci sono informazioni pubblicamente disponibili sul fatto che la proposta sia stata effettivamente attuata.

In Danimarca e Finlandia, una grande quantità di dati sanitari viene raccolta automaticamente nei loro sistemi sanitari nazionali ed è riutilizzabile per la ricerca secondo un modello di governance dei dati che si dice assomiglia al concetto di solidarietà dei dati. Entrambi gli stati hanno agenzie pubbliche specializzate nel favorire il riutilizzo di dati sanitari. Esse gestiscono le autorizzazioni per ricercatori esterni a riutilizzare alcuni dei dati sanitari nazionali, a condizione che la ricerca possa dimostrare di avere una relazione con l'interesse pubblico.

In Francia, è stato recentemente creato l'Health Data Hub, con l'idea di facilitare simbolicamente l'idea della donazione di dati. Questa agenzia gestisce e/o coordina il riutilizzo dei dati sanitari da una serie di importanti database sanitari, e dispone anche di una procedura per garantire la promozione di progetti di ricerca secondaria di interesse pubblico.

La Germania è un altro Paese in cui il concetto di donazione di dati è presente da tempo nel dibattito politico. Ci sono alcune modifiche normative recenti (e in corso d'opera) che cercano di implementare un sistema in cui i dati dell'assicurazione sanitaria e/o i dati della cartella clinica elettronica possono essere riutilizzati per la ricerca nell'interesse pubblico, con alcuni diritti residui (ad esempio, l'opt-out) per gli individui. Si prevede anche la creazione di un'agenzia speciale che gestisca alcuni aspetti normativi a questo proposito.

Infine, l'Unione Europea ha approvato una legge (Regolamento sulla governance dei dati) che rende operativo il concetto di altruismo dei dati in maniera legale. Tale legge prevede la creazione di organizzazioni per l'altruismo dei dati negli Stati membri dell'UE, alle quali gli individui possono donare i dati attraverso uno specifico modulo di consenso, e che possono poi concedere l'accesso per il riutilizzo (inter)nazionale di tali dati per scopi non profit. Tuttavia, finora è stata creata solo una di queste organizzazioni in tutta l'UE. La recente implementazione del Regolamento sullo Spazio Europeo dei Dati Sanitari a livello UE è destinata ad avere un'influenza su questi sviluppi.

Il Capitolo 4 sposta l'attenzione sulla donazione di dati nel contesto svizzero. All'inizio viene presentato che ci sono state alcune iniziative pionieristiche che hanno cercato di implementare in maniera simbolica la donazione di dati anche in Svizzera.

La prima è stata un progetto della fondazione Risiko-Dialog, che ha architettato due casi d'uso per l'implementazione dei dati come concetto simbolico. Un caso d'uso è stata la collaborazione con l'Università di Zurigo per indagare con un questionario durante il COVID-19 se i dipendenti dell'Università fossero disposti a fornire dati per la ricerca secondaria per uno scopo non commerciale (ad esempio, la lotta contro la pandemia), inquadrandolo come una donazione di dati. Molti hanno risposto positivamente, ma lo studio ha anche rivelato che - quando si trattava di donare/fornire realmente i dati - solo pochi lo hanno fatto. Questo dimostra che la intenzione di donare non significa che poi le persone doneranno dati effettivamente. Il secondo caso d'uso era una collaborazione con la città di Zurigo e riguardava la raccolta e il riutilizzo dei dati sulla mobilità per ricerche di interesse pubblico, riguardanti il clima e la salute pubblica. È stata avviata una campagna

per incoraggiare le persone a fornire dati sulla mobilità per il loro riutilizzo nella ricerca, e l'atto di fornire i dati è stato simbolicamente inquadrato come una donazione. I dati sono stati poi raccolti su un'applicazione appositamente progettata e dei questionari hanno chiesto alle persone quali fossero le motivazioni che le spingevano a donare i loro dati (ad esempio il fatto che i dati sarebbero stati riutilizzati per l'interesse pubblico).
Un'altra iniziativa svizzera è il Data Donation Lab dell'Università di Zurigo. Questo è stato appena creato per essere un knowledge centre per le iniziative di ricerca che inquadrano la raccolta di dati dai partecipanti e il loro riutilizzo come 'atti di donazione di dati' in senso simbolico.
Le caratteristiche comuni di queste iniziative che implementano la donazione di dati in Svizzera sono:

1) l'attuazione della donazione di dati è concepita come un concetto simbolico;
2) la sua caratteristica principale nella loro attuazione è l'atto di fornire dati per progetti/finalità di interesse generale/pubblico;
3) le persone, in quanto catalizzatori dei dati raccolti, sono al centro di tali iniziative, anche nel senso che i loro atti di donazione di dati devono essere consapevoli ed espliciti (non è stata adottata una politica di opt-out);
4) si concentrano su specifici set di dati e sul loro riutilizzo, e non sui dati sanitari in generale;
5) non considerano la donazione di dati postumi.

Oltre a queste iniziative che hanno cercato esplicitamente di implementare la donazione di dati, recentemente in Svizzera si sono verificati diversi altri cambiamenti politici rilevanti per riutilizzo dei dati in ambito di ricerca biomedica. Ad esempio, la Cartella Informatizzata del Paziente ha continuato la sua implementazione, ed è in fase di esame una modifica di legge che consentirebbe agli utenti di acconsentire al riutilizzo dei loro dati per la ricerca. Inoltre, i registri cantonali dei tumori dispongono ora di un quadro giuridico specifico che consente loro di raccogliere (e poi riutilizzare) i dati in modo automatico, con il solo diritto di opt-out per le persone. Recentemente è stata approvata anche una nuova legge federale sulla protezione dei dati, e l'Ordinanza sulla Ricerca Umana è ora in fase di revisione per consentire di fornire il consenso in forma elettronica. Inoltre, è stata proposta la creazione di una nuova legge quadro generale sull'uso secondario dei dati. Infine, iniziative come il Swiss Personalised Health Network e il tentativo di armonizzare i moduli di consenso generale tra gli ospedali universitari stanno avendo un impatto sulla governance nazionale dei dati sanitari.

Per quanto riguarda la Svizzera, l'ultima parte del capitolo fornisce una panoramica degli studi condotti finora sulla disponibilità della popolazione a condividere i dati per uso secondario, anche sotto forma di donazione di dati. Sono stati condotti diversi studi, con un design sia quantitativo (sondaggi nazionali) che qualitativo (study basati su interviste). In sintesi, risulta evidente che:

1) gli studi in genere non indagano il concetto di "donazione di dati", ma piuttosto la disponibilità generale a fornire i propri dati per il riutilizzo nella ricerca;
2) in genere c'è un atteggiamento positivo nella maggioranza della popolazione verso l'idea di donare i dati per il riutilizzo a scopi di ricerca, ma
    a. dichiarare l'intenzione di condividere i dati non significa necessariamente che i data verranno poi condivisi e

   b. gli individui spesso pongono delle condizioni al condividere i dati (ad esempio, dicono dipende da chi li conserva e/o da chi li riutilizza);

3) Gli studi indicano anche una scarsa comprensione di alcune questioni (ad esempio, anonimizzazione vs. pseudonimizzazione) e il desiderio di essere più informati su quali esatti progetti di ricerca basati sul riutilizzo dei dati vengono condotti.

Il Capitolo 5 offre una riflessione finale sull'impatto potenziale della donazione di dati, se ulteriormente implementata nella politica svizzera per la governance dei dati sanitari. Per cominciare, si riconosce che il concetto di donazione di dati rimane caratterizzato da molte incertezze, che renderebbero difficile l'implementazione nel contesto svizzero. Allo stesso tempo, è chiaro che una caratteristica distintiva della donazione di dati è quella di essere finalizzata a regolamentare l'uso secondario dei dati per ricerca biomedica nel pubblico interesse o per il bene comune. Questo approccio favorevole alla ricerca si abbinerebbe bene alla recente evoluzione di molti elementi del quadro dei dati sanitari svizzeri, tra cui la Cartella Informatizzata del Paziente ed i registri cantonali dei tumori. Pertanto, un'implementazione della donazione di dati potrebbe sostenere questi sforzi, oltre a chiarire alcune delle incertezze legali che ancora permangono in merito al riutilizzo dei dati da diversi database.

L'implementazione della donazione di dati in Svizzera richiederebbe ai decisori politici una serie di scelte. In primo luogo, dovrebbero decidere se implementarla come concetto legale o simbolico. In secondo luogo, sarebbe necessario stabilire se applicare il concetto solo al riutilizzo dei dati postumi o anche al riutilizzo dei dati di persone viventi. Ci sono diversi vantaggi e svantaggi per ciascuna di queste opzioni. Nel complesso, sembra che un'implementazione legale sia preferibile, in quanto offre maggiore certezza giuridica ed evita di fuorviare le persone. Inoltre, se implementata sia per il riutilizzo dei dati in vivo che per quelli postumi, il vantaggio sarebbe quello di avere un sistema normativo unitario per l’uso secondario per pianificazione, controllo e ricerca nel pubblico interesse. In questo caso, un potenziale Centro Nazionale per il Coordinamento dei Dati potrebbe svolgere un ruolo centrale, tra cui determinare quale tipo di uso secondario dei dati corrisponda all'interesse pubblico e a quali condizioni possono essere esercitati i diritti individuali (ad esempio, il diritto di escludere i dati dal riutilizzo). Inoltre, il Centro potrebbe contribuire a facilitare la mediazione tra le diverse parti interessate nello spazio dei dati sanitari e garantire un ampio coinvolgimento del pubblico nella comprensione della struttura generale di governance dei dati. Infine, qualsiasi implementazione della donazione di dati dovrà: 1) garantire che vengano prese in considerazione le lezioni di altri paesi che stanno sviluppando il loro spazio per dati sanitari (con infrastrutture, servizi e quadro giuridico); 2) chiarire l'interazione tra la donazione di dati e altri concetti esistenti nella governance dei dati sanitari (ad esempio, il consenso generale).

Un compito importante per il futuro è anche quello di monitorare l'evoluzione dell'opinione pubblica sulla fornitura di dati per il loro riutilizzo a fini di ricerca biomedica. Studi attuali mostrano un atteggiamento generalmente positivo nei confronti della donazione di dati per la ricerca, ma anche la presenza di molte preoccupazioni, soprattutto a seconda di chi riutilizza i dati. Inoltre, ci sono poche informazioni riguardo all'atteggiamento nei confronti della donazione di dati postumi. C'è anche la necessità di studiare il livello di literacy sanitaria digitale nella popolazione, poiché sembra esserci confusione sul significato di termini o procedure per la de-identificazione delle registrazioni di dati individuali. Infine, la ricerca futura dovrebbe anche indagare se esistano differenze culturali nelle preferenze riguardo la donazione di dati e soprattutto indagare non solo la volontà, ma anche l'effettiva predisposizione alla donazione. Quest'ultimo aspetto può essere studiato tramite questionari che riducano il rischio di social-desirability bias.

1. Introduction

The healthcare and biomedical research sectors are becoming increasingly digitalized both in Switzerland and worldwide, but governance of health data struggles to keep up. This problem is not uncommon: *in many technological fields the tendency of ethico-legal governance to experience difficulties in maintaining the pace of development of scientific advances has been observed.*[1] At the same time, the digitalization of healthcare and biomedical research presents its own set of problems. The latter concern, for example, the inherent complexity of these two fields, and the diversity of challenges that they have, depending on the country or context. One of the thorniest issues related to improving data governance in this field is *how to solve the apparent dichotomy between guaranteeing privacy whilst also favouring the bi-directional free flow of data between healthcare and biomedical research*. The first element refers to the need to leave individuals control over the use that is made of their (health) data, both because these are often highly sensitive and also because a nowadays established principle of medical research is that of giving individuals the choice whether (and how) to partake in it. The second element refers to the need that especially novel approaches to research (e.g. big data research, or large longitudinal epidemiological studies) require a constant flux of data from different sources (e.g. from the healthcare sector and back) and the collection and reuse of many types of medical information.

Many regulatory instruments, private and public initiatives, general policies and other ethico-legal frameworks are being developed to reconcile these two apparently opposing needs. Amongst them, one of the most prominent proposals that has received both academic and political attention in recent times has centered around *the concept of data donation for research*. However, despite being broadly discussed in academic literature, policy domain and even in some concrete legislative or data-infrastructure initiatives, *there is still a lack of clarity on the exact meaning of this concept,* as well as different interpretations of its features. Consequently, there are also many different ideas about its implementation.

In this context, *the objectives of this report are* to help define:

- what falls under the concept of data donation in relation to the secondary use of data for research, and
- what different interpretations and implementations of the concept exist.

Moreover, the report aims at connecting these issues to the current developments in terms of data governance in Switzerland, in particular:

1) to help with the ongoing work for a national consent management stimulated by the results of the work by the Federal Department of Home Affairs (Eidgenössisches Departement des Innern) in answer to the Postulat 15.4225 Humbel;[2] and
2) to support the ongoing work of the Department on the Postulat 20.3700 Bellaiche titled “Use of anonymised personal data in the public interest. Analysis of the feasibility of voluntary data donation”.[3]

In order to achieve these aims, the report is structured as follows. After this introduction, Chapter 2 will examine more closely the concept of data donation at a theoretical level, mostly from a policy and ethico-legal perspective. The objective is to clarify the meaning of data donation in the literature, as well as the many unclarities related to this concept. The chapter starts with a review of the origin of the concept (2.1), to then summarize the theoretical unclarities derived from the origin and development of data donation (2.2). It concludes by presenting a theoretical overview of other concepts that are often associated and/or conflated with data donation (2.3). Chapter 3 focuses on the implementation of data donation. Its objective is to show how, despite the theoretical unclarities listed before, the concept has been applied in some contexts. This reveals the feasibility of operationalizing a still undefined concept, but also demonstrates how remaining unclarities play a role in the implementation. In particular, the chapter starts with a preliminary distinction between two types of implementations – symbolic and legal (3.1). Outlining this distinction is necessary, in order to understand how differently the concept has been applied. An overview of different examples of implementation from the international context follows (3.2), ranging from single states, to the European Union. Chapter 4 moves to the Swiss context and it aims to show how the concept of data donation has already shaped some national or local initiatives (4.1), and how it is collocated in the broader context of Swiss health data governance (4.2). In Chapter 4.3, a review of the available evidence concerning the readiness for data sharing and data donation in the Swiss public and their attitudes towards the topic is presented. This element is crucial, since it gives an idea of where society stands in respect to initiatives aiming at changing the balance between individual control and free data flow in research and also shows existing gaps in knowledge of public attitudes. Chapter 5 finishes with some reflections on the potential impact of data donation in Switzerland, in particular in respect to the feasibility of a large-scale implementation of the concept and its interaction with other aspects of data governance. Chapter 6 contains some final remarks and is followed by an appendix with additional a glossary.

2. The concept of data donation

In this chapter, we focus on an analysis of data donation at a theoretical level, i.e. with respect to the definition and the notional understanding of the concept, rather than on its implementation. We start by reviewing and explaining how the concept originated, as the context of its creation is crucial to understand both its content and the challenges in defining its boundaries. We then summarize the conceptual unclarities related to data donation. In this way, we explain how *the theoretical and academic origin of the concept and the vagueness of many of its inherent features have contributed* to:

1) making it applicable to (and used in) many policy and project-related discourses;
2) generating several misunderstandings about what data donation actually entails, and how it correlates to other related new and traditional concepts in health data governance for research.

We then turn to these related concepts, illustrate their content and explain why they relate to data donation, namely the fact that they are underlined by a common goal and – in some cases – also by some common principles.

2.1 The origin of the concept

The first mention of the concept of data donation

The *first appearance of the concept of data donation* resides in a small commentary by Taylor published in the prestigious medical journal “The Lancet” in 2000.[4] Here, the author simply built her reasoning on a practical intuition. She observed that many brain researchers also act as participants for the research of their colleagues, for example by providing their MRI scans as control participants in their studies. She then observed that much of these data are used once, but then – once the person having provided the data passes away – they get lost. She thus “propose[s] a voluntary data donors scheme, analogous to the organ donor scheme currently operating in the UK and other countries” whereby “Participants would carry a card summarising what data are held on them by which institution” and, if they die or develop a brain disorder that makes them uncapable, “their doctors could use the card to contact the institution and request the data” they had previously provided. The author admitted that “there are issues of data ownership, and confidentiality, both academic and medical” with her proposal, but believed that these could be overcome with appropriate governance. In this first delineation of the concept, some essential features of what data donation represents were already clear. Rather than a fully thought-through ethico-legal concept, *data donation was conceived as* (and to a large extent has remained) *a proposal to offer a common-sense solution to a pragmatic problem in respect to the availability of data that would otherwise likely be discarded*.

Data donation gets defined in the academic debate

After this initial mentioning, the concept of data donation remained absent from policy and academic debate for some time. Then, in the 2010s, the increasingly large capacity to save and process data, alongside a broader policy discourse around the necessity of improving digitalization in the biomedical sector brought it back. It was once again in the academic context that the idea of data donation was brought to the fore in 2015. In publications for

EMBO reports (an influential academic journal in the biosciences)[5] and again in the Lancet,[6] Shaw and colleagues spoke of *data donation after death as a common-sense solution for an apparent contradiction*. Namely, the fact *that health data of deceased persons are often difficult to use for research purposes, even though they are arguably less confidential than personal data about living people*. The authors spoke of the difficulties in conducting medical research projects with data from deceased persons in contexts like the United Kingdom and Germany, such as the fact that researchers need to prove that it was impossible to obtain consent from the person whilst alive. They then argued that much of these data actually go to waste due to such difficulties. They thus, similarly to Taylor, but not only for brain-related data, suggested that governments implement a 'Data donation after death scheme'. The authors recommended it should function like organ donation: *a registry should be implemented, where people are asked – whilst alive – whether (and which kind of) their health data can be used for research post-mortem, also with the possibility to indicate for which kind of projects these data should be made available*. They insisted that this is better than the current data governance system, which leaves ethico-legal uncertainties and often puts researchers in a difficult situation as regards the reuse of health data for a new project. *They also stressed that one further feature of data donation should be to highlight the charitable and common-good character of providing data for research*. Policymakers should advertise the scheme of data donation (and related registration) as something that is done "in order to help present and future generations to live longer and better lives". Interestingly, they also maintained that "Whether data donation should ultimately be used more generally to govern the use of living patients' data is an important question", but then concluded that "we would suggest that data donation is used only posthumously *in the first instance*" (our emphasis).

This more advanced proposition o*utlined already the main features of what data donation could look like, as well as presenting the first dilemma related to the implementation of this concept*.

a) For a start, data donation is presented almost as a carbon-copy of the institute of organ donation, but applied to the digital, rather than the physical body of the person. The conceptualization of data as (digital) body has already been discussed. Consider, for example, biobanks: they contain both body parts/tissues and health related data. There, tissues are protected due to the (health) information that can be derived from them. Equally, health data are protected because they reveal something very tangible and private about the body of individuals. This blurs the line between physical and digital. There are, however, many issues problematic related to conceiving health data as (digital) body parts[7] and – consequently – in trying to 'translate' the legal institute of organ donation into that of data donation.
b) Moreover, the scheme of data donation is presented as one that could offer an easy way to regulate the transfer of data to researchers after the death of an individual. At the same time, it is also described as something that could be used to transfer data between living individuals (just like – also for the donation of selected organs – it is possible to do it both post-mortem and during life). However, neither the transfer of health data of the deceased to research, nor the transfer of data from living people are unregulated fields. Statutory legislation, together with legal interpretation and other regulatory instruments of research data governance (e.g. guidelines from ethics committees), already constitute a data governance architecture for these fields. For example, the provision of data for secondary research purposes can already be done through: the legal basis of specific

consent; or, in certain cases, broad or general consent; or, in others, also without consent but with an exceptional authorization by ethics committees.[8] It is thus unclear to what extent data donation would supplement, substitute or complement existing data governance mechanisms for the transfer of data. One possibility is that data donation would be limited to govern the transfer of data for public/common interest purposes – as briefly hinted by Shaw and colleagues.

c) Third, it seems evident that data donation was originally conceived as pragmatic and common-sense proposal from the academic literature, rather than concrete proposal in terms of policy. It follows that there are many open questions as to how this could be implemented, starting from the lack of a clear and uniform definition.

The conceptual work on data donation was brought to the fore once again from the late 2010s along two main channels:

- a collaboration between the University of Oxford and Microsoft, which tried to better define what data donation is and how it could be implemented in an ethical code;
- the response to the COVID-19 pandemic, which in many contexts prompted researchers and policymakers to start campaigns of data collection for secondary (public health) research and surveillance purposes that were labelled with the term ‘data donation’.

The Oxford-Microsoft collaboration

The Oxford-Microsoft collaboration was started in order to develop more details on how the concept of data donation could be conceived from an ethical perspective. More specifically “the goal is to explore ways in which citizen participation in research efforts may be supported via ‘data donations’, and to shape best practice with regards to respecting individuals’ rights as well as ensuring proper regulatory oversight of existing and future data exchange partnerships between governments and tech companies.”[9] Moreover, the project wanted to “investigate the possibility of a European Code for Data Donation, its feasibility, its advantages, and the possible difficulties that may be encountered in its formulation and adoption.”[10] A central deliverable of the initiative was a book titled “The Ethics of Medical Data Donation”[11]. This collected several academic researchers’ (mainly from the field of bioethics and data governance) perspectives on the concept of data donation from a general ethical and philosophical point of view and on the potential issues with future implementations. In the introduction to the book, it is explicitly said that the idea of the editors is to pick up from where Shaw and colleagues left the discussion (see above), since “Arguments for facilitation of [data donation] have been advanced but so far have not been implemented”.[12] In the next paragraphs we summarize the most relevant findings of various chapters of the book, focusing on what is relevant for this report and the definition of data donation.

Within the chapter authored by Prainsack,[13] the author made *three important points on what data donation is and how it should be conceptualized*. She emphasized that:

1) There is a lot of conceptual unclarity on what data donation is, since this term is sometimes used only for the posthumous giving of data, and sometimes also for the living context, as a sort of synonym for data sharing.
2) If we are to take the word ‘donation’ seriously, we must remember that donations (as legal instruments in the non-data context) are embedded in an idea of relationality and contain an element of reciprocity, albeit non-commercial. In other words, *someone donating an item is NOT simply transferring it to another person without*

conditions. There are expectations attached to donations, in particular as regards the use that the donated item will have. Thus, *if we want to truly speak of donations also in the context of data, such aspects (e.g. the expectations that the donated data will be used for specific purposes and is not a blank check to do whatever with data) need to be respected*. Donations are thus rooted in principles of reciprocity and solidarity, and in the expectations that “my data should create value for others too”[a]. These features, as well as the symbolic, mutual and public nature of donations is also mentioned elsewhere in the book.[14]

3) Data are a different type of resources as compared to anything else that can be donated (since it cannot legally be owned).[13] Indeed, in the legal sphere the use of the term ‘donation’ in relation to ‘data’ has been criticized and called an oxymoron, given that the (legal) term ‘donation’ seems to imply the transfer of ownership, but personal data are not property.[15]

In the Chapter by Hummel and colleagues, they tackle also another important aspect of data donation, i.e. the role of consent.[14] They remind us that many possibilities to provide data for research already exist, including various forms of consent (for a single project, broad, etc.) and reflect on how this fits in with the discussion of data donation. Their analysis raises an important question: *would data donation be simply the symbolic name of an act of “giving data” that is actually based on (traditional) consent? Or would data donation be a separate (legal) entity, which maybe still requires consent, but of a specific nature and extent*?[b]

Another important aspect mentioned in the book is the question of whether posthumous data donation should be treated in the same way as data donation between living people, with Harbinja arguing convincingly against it.[16] She reminds, for example, that deceased individual cannot be harmed by data misuse (if it were to happen) in the same way as living individuals.

The Chapter by Sorbie[17] mentions another important issue related to data donation. This concept is often invoked together with many others (see Chapter 2.3. below), which share similar underlying principles, such as that they “suggest admirable exercises of autonomy for the sake of the common good”. She also reminds us, in relation to the role of consent for data donation, that if this is constructed too widely, it risks to take the donation too far away from intentions and expectations of the donor. If, on the contrary, it is constructed too narrowly, it may exclude from data usage certain secondary research projects that the donor would have approved of, but simply did not indicate explicitly in the donation. She also *proposes to design data donation as something existing alongside current legal basis for providing data for research (e.g. consent), but should be used only for giving data to research aimed at serving the public interest*.

The book ends with what the authors call an ethical code for data donation, which sets out a working proposal on how data donation could be governed.[18] The code *focuses only on posthumous medical data donation, and authors stress explicitly that data donation is a term that should be used only to describe the ‘giving’ of data for secondary research purposes with respect to deceased people*. They argue that *any other act of giving data for research whilst being alive should be labelled as “data sharing”.*[19] Moreover, the code – rather than being a detailed document on how data donation could be implemented in a specific context – simply provides general (ethical) principles alongside which data donation after death can

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[a] This is a quote from the chapters. See also the discussion in Chapter 2.3

[b] More on this in Chapter 3.1

be operationalized. The code also includes a draft of what an “authorization form” to use for posthumous data donation could look like.

The concept of data donation during COVID-19

The COVID-19 pandemic was another catalyzer to advance the discussion on data donation. Indeed, given the need of data of a different nature (e.g. on infection, but also on people’s mobility) that was present for public health reasons, data donation was one of the frameworks used to label some initiatives related to data collection for research aimed at the common good (i.e. fighting the pandemic). Interestingly, *in this context donation was used mostly for labelling projects where data was collected from living individuals, thus sidetracking from the discussion of the Oxford-Microsoft collaboration, which mainly aimed at reflecting on data donation as a concept to favor secondary research with data of deceased people*.

One popular example of the use of the concept of data donation during the COVID-19 pandemic is the experience of the German Corona Data Donation project. This was based on an app created by a famous public health institute, through which participants could ‘donate’ their health data (collected through their own wearables) for secondary research uses.[20] *This is an example of what we define below*[c] *as a symbolic implementation of data donation*. In the app used for the project, health data were still collected based on traditional specific consent,[21] but the act of giving data was framed as ‘donation’ to underline the altruistic nature of the provision of data, thus encouraging participation.

Or else, there were reports indicating that various United States Tech Companies added to their own apps the possibility for people to donate data that could be deemed useful for fighting the pandemic.[22] Microsoft also conducted a large survey in the United States to explore whether people would be willing to donate their health data in this manner – once again, referring to data donation from living people, and not posthumous.[23]

2.2 Conceptual unclarities

As emerged from the discussion of the historical development and conceptual debate around data donation, this term and its boundaries are riddled with many conceptual unclarities. To summarize, the major ones are:

1) The *absence of a uniform definition* of the concept and its basic features
2) The *diverging opinions* (especially between academic/scientific discussions and first implementations) as to whether data donation should be used only in the context of the *transfer of data between living people*, or exclusively as a data governance instrument for *data of deceased people*
3) The *role that consent should have*, and especially whether data donation should be conceived as complementary or alternative to the existing legal bases for the transfer of data and reuse in the research context.
4) There seem to be some basic agreement that data donation should be used *only in the context of giving data for secondary research serving a public interest*. It is however not clear how broad this could be conceived and – especially – whether

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[c] See Chapter 3.1

individuals should be consulted on the content of that interest. As it will be clear below in Chapter 3.2, different countries solved this question in a different way.
5) The extent to which data donation could be applicable is also uncertain. All health and health-related data? Health (related) data contained in specific repositories?
6) Its relation with adjacent developing concepts is also unresolved (see 2.3)

One reason why many unclarities could develop in the first place and now still persist are due to the fact that *there was never an agreement on the basic definition of data donation*. This led to the term to be used in different contexts to frame either normative discussions on how to best regulate the sharing of data, or practical discussions on how to use the term to depict data collection efforts in specific projects. In consequence, data donation can be used in two interrelated but very different meaning, i.e. either as a legal concept or as a symbolic concept (more on this in Chapter 3.1). Furthermore, the term is also often confused, conflated and/or used interchangeably with other comparable concepts related to how the governance of the collection (and especially reuse) of data for secondary research purposes could be re-arranged.

2.3 Related concepts

One of the reasons why the conceptualization (and implementation) of data donation is riddled with so many uncertainties is that *there are many related concepts that are associated with it*. These are also *sometimes even used as (improper) synonyms* of data donation. This is also due to the fact that there is no uniform definition of data donation and that even its most basic features (can it be used only for the reuse of data of deceased persons, or also living ones?) are not entirely resolved. For these reasons, we give below a comparative overview of the different terms related to data donation (first in Table 1 and then in the text). We also reflect on why they are sometimes mentioned in connection to each other, namely that they all are based on similar underlying purposes and principles.

Table 1. Comparing data donation with related concepts.

Data donation	Data Philanthropy	Data Solidarity	Data Altruism
The concept describes the idea of providing data for secondary use in research, mainly after the death of the 'donor'. The research should correspond to some notion of public interest.	The concept describes the idea of providing data for secondary use in research. However, the data is provided not by the individuals themselves, but in bulk by companies who control it. Even here, provision of data is only for secondary research in the public interest.	The concept aims to be a guiding principle to re-organize data governance. It calls for removing red tape for secondary uses that promote public value. Moreover, it calls from substituting individual control over data with collective control.	The concept describes a new legal mechanism created by the EU to allow citizens to give data for secondary uses for non-profit purposes. Data is provided by individuals through "data altruism consent", and is managed by specific organizations.

Data Philanthropy

One of the first similar concepts which emerged in the discussions related to data donation is that of *data philanthropy*.[24] Data philanthropy refers to the idea of private companies giving data to public institutions and/or making it publicly available for the common good (e.g. to make secondary health research). The key difference with data donation is allegedly that, with data philanthropy, *it is private companies rather than individual providing data, which is often bulk anonymized or aggregated data rather than personal one*.[19] However, this distinction is not always maintained and sometimes data philanthropy is also defined as "the donation of data from both individuals and private companies." [24]

Data solidarity

Another concept that is thematically related to data donation is that of *data solidarity*. This refers to the idea of developing a form of data governance with "collective forms of control, responsibility, and oversight"[25] to ensure that data is used for the public good. In a data-solidarity-based governance framework, individual autonomy and control over uses of data is present, but secondary in respect to collective control. This entails that uses of data that "would create considerable public value […] receive more public support by removing red tape or by providing financial and practical assistance".[26] Moreover, policy should empower individuals to exercise collective governance by giving them the power to control which ones are the "public value uses" for which red tape should be removed. The proponents of data solidarity mention the Nordic countries (Finland in particular) as an expression of data solidarity (more on this in Chapter 3.2).

Data altruism

Furthermore, recent policy and legislative developments in the European Union have also introduced the concept of *data altruism*. Although this will be better explained in Chapter 3.2, here it suffices to say that it represents another instance of developing a concept to embed in data governance to try and improve the availability of data for secondary research to the benefit of the community.[27] Data altruism is also often conflated with data solidarity and considered a similar term. It is also important to say that the insistence by the EU on this concept rather than data donation has been justified as follows:

> "both the terms data altruism or data solidarity have been used in preference to the term data donation as the latter implies ownership transfer - one cannot give away fundamental rights on his or her personal data."[28]

Other established ethico-legal concepts related to data donation

On top of these emerging concepts, it is important to note that there are many other concepts in data governance that often come up in relation to data donation. Undoubtedly, the most important one is that of *specific consent*. In data governance for research, consent is a contested topic, in particular due to the fact that it stands at the crossroad of research ethics and data protection regulation.[29] In fact, informed consent has traditionally been a central pilaster in research ethics and data protection law, but it is challenged by the development of data-based research. Here, there is no physical interference with participants' bodies, and only processing of their data (e.g. retrospective epidemiological studies). Informed consent is also one of the main legal bases upon which the processing of data (including for research) can be justified, but it is not the only one. The presence of a public interest or an explicit authorization by a law are (almost) universally considered as alternative legal basis that can justify the (secondary) processing of data for research.[30] This is the reason why – especially for biobank research and data-based research – alternative models to the traditional informed consent or specific consent (i.e. one that should be tied to a specific project, and thus re-obtained every time data is used for a new purpose) have been developed. These include dynamic consent and broad consent.[31] Dynamic consent consists in the development of consent procedures that allow research participants to personalize when and for what they want to be asked consent as well as being dynamically informed about results of data analysis.[32] This model has been further developed into slightly different models: meta-consent, where participants are allowed to determine which model of consent they want to apply to different scenarios;[33] or value-based consent, proposing to turn participant preferences and values into an individualized matrix to determine the consent preferences of each person[34]. Broad consent (sometimes also called general consent, as the two terms are considered close synonyms in the international context[35,36]) refers to a consent (often given during hospital treatment or participation to a biobank study) for the reuse of data for several research projects within a certain scope.[37] They have also to be distinguished from blanket consent, which is the consent to allow any reuse of data in any field, and often criticized from an ethical point of view.[38]

Consent (and its different forms) is related to data donation due to the fact that they may play a role in it (see previous Chapters). Indeed, it is normally argued that the *declaration of will* that individuals would have to express to provide data for reuse (in a situation of data donation) should be expressed through consent. *It is not, however, clear whether data donation would have to be built on top of consent, or whether it would substitute it*. This also depends, as illustrated in Chapter 3.1, on whether data donation is implemented as a legal or symbolic concept. It is, however, very likely that consent (or some other form of individual declaration of will - *Willensäusserung*) will play a central role in data governance, since there is a widespread desire in the public to keep some sort of oversight on the use that is made of their personal health data:

> "While there are still ongoing discussions on what would be the best option for data sharing: the use of dynamic consent, broad consent or data donation without consent, it seems that public preferences for a certain level of control over their data, regardless of the lawful basis relied upon [for data processing in research], support a continued role for consent to maintain trust in research"[29]

A short summary of the main similarities, differences and connections between the different consent models and data donation is presented in Table 2 below.

Table 2. Comparing data donation and different consent models

Data donation	**Specific consent**	**Dynamic consent**	**Broad consent**	**Blanket consent**
If implemented, data donation would allow individuals to give easy access to their data (especially post-mortem) for secondary research uses in the public interest.	It is a legal basis for the processing of data, which can sometimes also be used to justify secondary processing of data for research. It gives the permission to reuse data only for a particular and pre-defined purpose, and thus may have to be obtained several times in case of several reuses.	It is sometimes implemented in the policy of databases or biobanks. It allows individuals to be re-engaged multiple times (rather than only once) to determine their own views on the use of their data for research. It also envisions a more interactive exchange with individuals (e.g. keeping them informed about some research results etc.).	It is sometimes implemented in the policy of databases or biobanks. It allows individuals to consent to broad, future unspecified secondary research projects within a defined area (e.g. cancer research). Sometimes it is also called general consent in the international context.	If implemented in law/policy, it allows the reuse of data for any secondary research use within the limits set by the law/policy itself (and not the preferences of the individual). This is close to the General Consent concept as conceived in Switzerland.[39]

A common ground between different concepts

The reason why all these concepts (apart from specific consent) are related to data donation resides in the fact that they are all responding to the same underlying objective. *They are attempts at developing new models of data governance for research uses of data that are not based on the necessity to ask individuals for consent every time their data is reused*. In so doing, they try to re-module the way people can keep some form of control over their data, without giving them the same extent of powers as asking for specific consent for every project would. Moreover, data donation, data philanthropy, data solidarity and data altruism are also united by a similar underlying principle. *They all resort, both in their framing and also in their rhetoric, to the idea of data usage for the common good, for non-profit initiatives, public interest and non-commercial purposes*. Indeed, *solidarity, donation, philanthropy and altruism are all terms with a strong evocative power that suggest data will be provided for a good cause and thus enhance the reliance on the goodwill of people to contribute data*. This is also confirmed by the fact that they are often used in the context of citizen science, i.e. attempts at involving more directly (both in terms of providing data but also governance) single individuals in conceiving and carrying out projects. Needless to say, *this common basis also creates confusion and conflation of the different terms both in the view of policymakers but also in the scientific literature*. This confusion is evident from, for example, a quote from a scientific paper, where many of these concepts are presented simultaneously and almost used as quasi synonyms:

> "As a complement to citizen science, the ability of patients to be 'data donors' lays the foundation of a new kind of participation in clinical research—data altruism, where the patient contributes his or her clinical data either broadly (broad consent) or to specific projects."[40]

3. Implementing data donation

3.1 A preliminary distinction

Before turning to an overview of how different attempts at implementing the concept of data donation can be seen in different countries, it is important to point out an important preliminary distinction mentioned above. Specifically, *when considering the implementation of data donation, it is crucial to distinguish between legal and symbolic implementation*.

A *legal implementation* refers to situations where data donation is implemented directly in law and/or regulation and a clearly defined legislation/policy exists, whereby it is possible to say "data was provided through the regulatory institute of 'data donation'". This would correspond, roughly, to implementing what we now have for organ donation, but also for data. It would entail having a specific law (or legal rule) that defines what data donation is, its limits, and thus also constitutes a legal basis whereupon data can be processed. For example, policymakers could implement a set of legal rules that would then legitimize researchers to say (in their protocols, data management plans, and ethics review documents) that they are legitimized to process data because it was provided through the legal institute[d] of data donation.

On the contrary, a *symbolic* implementation of data donation (and related concepts) corresponds to all those operationalizations where no law or legal rule is passed, but existing legal basis are reframed (as part of a specific initiative or projects) by referring to data donation. For example, policymakers could start calling the act of providing data to national cancer registries as an act of "data donation" *symbolically* and *instrumentally* (due to its positive connotation) to favor a positive public attitude towards the giving of data to these databases.

One *advantage of implementing data donation as a symbolic concept* is that no legal adjustments are needed. Policymakers (or other responsible stakeholders) could simply organize the collection and reuse of data for research based on the already existing legal framework, *but then advertise their campaigns of data collection as requiring a symbolic act of data donation by people*. This would also avoid the intrinsic difficulties that implementing data donation as a legal concept entails, for example the fact that one would have to reckon with the fact that data are not property and cannot therefore legally speaking be donated (since current legal doctrine understand donation as a legal instrument to transfer the property of an object).

On the contrary, *the advantages of implementing data donation as a legal concept* entail that through an explicit regulation it would be possible to clearly delineate what data donation is (and what it is NOT – e.g. by explaining the relation with existing legal concepts such as general consent). It would therefore be possible to further specify what are the criteria that need to be satisfied for researchers to be able to rely on data donation, for example the fact that their research should serve a public interest. Finally, it would be possible to specify what is the role of individuals in respect to data donation, i.e. whether they should provide an

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[d] A legal institute (German Rechtsinstitut) can be described as a Legal construct developed (and bindingly applicable) in legislation, legal practice and legal doctrine with certain characteristics for the systematic and appropriate recording and treatment of certain life circumstances.

explicit authorization for researchers to use their data through data donation (opt-in solution) or if an authorization can be presumed whenever secondary research is in the public interest (opt-out).

Thinking about *legal* and *symbolic* implementations of data donation (and related concepts) is also a useful way to categorize and understand what other countries are doing in this respect. Moreover, it helps to understand that there is a difference between using a certain *symbolical/rhetorical* frame, such as that of data donation, to describe existing policies and governance instruments related to data, and actually creating a *legal/regulatory* institute corresponding to data donation, with its precise and distinctive features.

3.2 International examples

In this Chapter, an overview of initiatives from different countries that correspond to the implementation of data donation or related concepts is presented. *The objective is to show how different policymakers and other stakeholders have tried to go from the definition of data donation at a theoretical level to the actual operationalization of the concept*. In this way, it is also possible to get an idea of the challenges and opportunities that different contexts offer, and to consider to what extent Switzerland can learn from international experiences. In Table 3, the most important information for each country/context are summarized. Moreover, an explanatory Info-Box is added to succinctly present the role that different public institutions offer in respect to managing secondary use of health data for research in those countries having it.

Table 3. Overview of countries implementing data donation and related concepts

Context	Data donation (or related concept)	Posthumous or in vivo	Relation to consent and retraction thereof	Involved data-intermediaries and/or other institutions	Further notes
England (ca. 56 million inhabitants)	*NO explicit "Data donation"* regulation exists, but NHS rules allow posthumous re-use of health data for research unless patients opt out.	These rules concern mainly the use of health data held from the NHS *post-mortem*.	*Patients are allowed to opt-out whilst alive* through a National Opt-out register. If they opt-out, data are not used during and after their death.	The *national Data Opt-Out*. This is managed by the NHS and it tracks opt-outs, as well as exceptions to it.	Despite NOT being explicitly called "data donation", this system mirrors many ideas of (post-mortem) data donation.
Netherlands (ca. 18 million inhabitants)	Idea of a *"data donation" app* to facilitate research (explicit mentioning of "data donation").	The app was meant to allow the donation of data *during life*.	Patients would be allowed to provide series of health data through an app *by consent*, which would then allow access to research for the public good.	The *platform "Donata"* which would decide which research projects are in the public interest, and can thus require donation of data through the app.	The system was proposed, but not implemented in practice.
Denmark (ca 6 million inhabitants),	Nordic countries generally are said to *embody the idea of "data solidarity"* with their national data infrastructure.	Its data infrastructure generally allows the use of health data for research both in-vivo and post mortem.	*Citizens are NOT asked for their consent* to collect and share data for most data-based research projects. *They can opt-out only from a limited number of uses*.	The national data/statistics agencies (esp. the Danish Health Data Authority) are generally involved. For more details and examples see Info-Box.	This system has been in place long before the discussion on data donation and related concepts started.
Finland (ca. 5,5 million inhabitants)	Nordic countries generally are said to *embody the idea of "data*	Its data infrastructure generally allows the secondary	*Citizens are NOT asked for their consent* to collect and reuse data for	Findata plays a central role. For more details and examples see Info-Box	This system has been in place long before the discussion on

	solidarity” with their national data infrastructure.	use of health data for research both in-vivo and post mortem (presence of specific legislation)	most data-based research projects. National authorities manage the limited rights to restrict processing or opt out.		data donation and related concepts started, but developed recently (e.g. creation of Findata)
France (ca. 68 million inhabitants)	The developing health data infrastructure draws on the *symbolic framing of data donation* to stimulate citizens support for health data reuse.	The developing infrastructure concerns both in-vivo and post mortem *depending on the single database*.	*Consent-issues are managed at a decentralized database level*, and thus differ greatly.	The *Health Data Hub* was built as an intermediary for regulating access to the greatest majority of health databases. For more details on its role, see the Info-Box dedicated to it.	The system is currently in development, thus subject to change.
Germany (ca. 84 million inhabitants)	Governmental report suggested to introduce *“data donation” as an explicit legal pathway* (see chapter below).	The idea is to allow the donation of data *during life*.	The proposal is that donation would be based automatic, with an *easy-to-exercise right to opt out*.	It is likely that the *Forschungsdatenzentrum Gesundheit* will play a key role.	The system is currently under development, thus subject to change.
European Union (ca. 448 million inhabitants)	The Data Governance Act introduce the *legal mechanism of “data altruism”.*	The system was designed to allow the donation of data *during life*.	Donation of data is based on “Data altruism consent”, but the form has not been developed yet.	*Data Altruism Organisations* are supposed to play a central role, but they are still being created.	The system is currently under development, thus subject to change, especially as the European Health Data Space also advances.

England and reflections on posthumous data donation

Considering the United Kingdom, and England more specifically – since law and governance differ with those of other constituent countries such as Scotland – as an international example is particularly important. Indeed, it was in this context that some of the original academic conceptualizations of data donation were conceived. This country has been subject of a detailed analysis mainly led by the work of Harbinija and Pearce, two experts in data protection law. They published two studies in which the subject of analysis was whether there is anything the resembles data donation (and posthumous data donation in particular) in the English data governance and regulatory system.[41,42] In their understanding, data donation is a “practice [that] enables individuals to employ their altruistic motivations and aspirations by helping them participate in ‘citizen's science’ and medical research”[41] . They consider it particularly useful in case of posthumous donations, given the lower privacy risks that this entails (as compared to data donation between living people).[e] As a consequence, one of these studies defines Posthumous medical data donation as “the philanthropic notion of donating personal data pertaining to one's health and medical conditions, post-mortem for the purposes of non-commercial medical research”.[42]

In the analysis of English law and governance around these issues, the aforementioned lawyers underline that the handling of data post-mortem is normally not covered by data protection law, since this normally refers to personal data of living people. However, a case of data donation (in a legal sense) can be found in the law regulating access to people’s health record collected in the National Health System (NHS). The latter allows the use of

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[e] Some risks remain, especially in case of data that reveals details about descendants (e.g. heritable genetic data).

these data even post-mortem, but also permits individuals to opt-out from this possibility whilst alive.

Info-Box on the National Data Opt Out by NHS England

The National Data Opt Out is a service by NHS England, through which individuals can require their NHS data to be excluded from secondary research uses.

Individuals can use this opt-out service if they are 13 years of age or older, and they can opt-out from secondary data uses through the NHS app, the NHS website, by phone, email or post.

The opt-out is valid also post-mortem, and it concerns all NHS data collected during treatment. It applies prospectively.

The latter service is now explicitly organized in a system called "National Data Opt-Out", a technical and regulatory infrastructure that governs the possibility for residents (under certain conditions) to withdraw some of their NHS health data from the use for secondary purposes including research.[43] It is also important to note that in his analysis Pearce highlights that "no jurisdiction anywhere in the world that operates [as of 2022] a bespoke regulatory framework for PMDD [Posthumous Medical Data Donation]".[42] This confirms what we outline in this chapter, namely that there is a scarcity of international contexts that have implemented *explicitly* data donation as a legal concept, and – the few that exists – are very new.

Another important contribution of this reflection from England on data donation consists in defining what the role of consent could be for posthumous medical data donation. More specifically: should consent always be required from individuals before they die, in order for their data to be used after death? Or should an opt-out be implemented? The solution proposed is that of an opt-out design, given the absence of strong personal autonomy concern in case of post-mortem use. It is however also underlined that having an opt-out solution may turn the concept of data donation "from a notion primarily associated with the 'donation' of one's medical data, to one better described as involving such data being 'taken'".[41] This issue is relevant also for the broader debate of data donation amongst living people: would the design of a regulatory system (data donation as a legal concept) based on an opt-out solution preserve the feature of willingness and voluntariness that are generally and intuitively associated with the act of donating?

Netherlands and the proposal of Donata

The Netherlands had a small initiative that tried to implement a specific understanding of data donation in the symbolic sense as a frame for a potential data collection initiative. More specifically, in 2019 a national think-tank was organized to try and propose innovative solutions to optimize communal life in a digital society.[44] The initiative was sponsored by many important stakeholders in the health care sector. One of the proposed solutions was called Donata, a mobile application that would allow citizens to make data available in a more centralized database, especially data collected through their digital lives (e.g. through wearables or other digital service providers).[45] Donata was envisioned as a platform where research agencies oriented towards the public good could publish requests for specific type of data, with also an explanation of what data they would need and their purposes. Users of the app would then be able to see such requests and support them by providing the quested data through their smartphones, freely choosing whether/which data to donate. If the amount of data necessary for the research project would then be achieved, research institutes would pay the platform a fee to help recover the costs sustained for allowing citizens to provide their data.

The initiative suggested to use explicitly the frame of data donation in a symbolic sense, meaning in particular that:

1) the (legal) basis for collecting/reusing data on this platform would still be the consent of the individual who uses the app and loads the data;
2) the reference to “donation” was used to emphasize the charitable/non-profit purposes why data would be collected and to give a positive/altruistic frame, so that more people would give their data.

No information is available whether (and to what extent) the platform was subsequently implemented.

Denmark and Finland: the Nordic approach

Other international examples in how some underlying principles of data donation are implemented in practice are that of Denmark and Finland. *These do not have institutions, projects or initiatives that draw heavily and explicitly on the concept of data donation*. However, *they possess several institutions and policies which embody the principles connected to data donation that we listed above in Chapter 2.3 (reuse of data for research in the public interest) and in particular relate to the concept of data solidarity*. In fact, these countries have many national (or regional) databases that collect health related data for purposes of public interest, and they do so to expand the concept of solidarity that characterizes their healthcare systems to the medical information sector.

Taking Denmark as an example, this country has one of the most advanced and interconnected health data infrastructures in the world. Data are not only automatically collected in specific registries and databases each time a resident comes into contact with the healthcare sector,[46] but a great deal of health data is then also directly accessible and controlled by individuals themselves through an appropriately designed data access platform for patients.[47] The majority of these data can then be reused through two main centralized and secure access points, called Statistics Denmark and, especially, the Danish Health Data Authority.[48] Access for reuse can only be requested by academic and public funded researchers (whence the common/public interest feature of this system) for projects that serve the public health improvement, quality control and health research for the Danish system. Access for researchers based at a private pharmaceutical company is not possible in every case, since as a norm an affiliation with a public research institution is required. The whole resident population is covered by these databases, thus reinforcing the solidaristic framing of the system, as data collection is not based on the legal basis of consent, but on other legal bases focused on public health objectives.[49] These features of the

Info-Box on the Danish Health Data authority

The Health Data Authority is a key public institution in the Danish health infrastructure. Through its research services, it is possible to file a request for accessing many of the routinely collected health data in Denmark.

Researchers (provided they satisfy certain requirements) can request access to the Authority, who evaluates every request and the provides access against a fee.

In general, only researchers based in Denmark and at a public research institution (e.g. public university) can get access to data for research through this authority.

Data is collected and reused based on legal authorization and not on consent. In some limited cases, individuals can object to the secondary processing of data.

Danish system have led to the situation where *a report on the rules on the processing of data commissioned by the EU defined Denmark as an example of the implementation of data solidarity*.[28]

Info-Box on Findata

Findata is the Finnish agency responsible for issuing permits for secondary use of social and health data from a variety of data sources in Finland (some controlled directly, some indirectly).

It also offers a secure environment for the processing of data, and charges for the various services it provides.

In principle, it can provide access for a variety of purposes (but not marketing or insurance rating) including private and public research. A log of all data permits issued is available online.

It also manages individual rights. These include the right to object to the processing, the right to rectify data and the right to access.

Systems based on similar principles are also in place in the other Nordic countries. For example, Finland often comes across in the scientific and popular press, given their development of *Findata, an agency responsible for managing the access for secondary use (including research) of many data that are collected in different databases by state institutions (including also health data)*.[50] This agency also has set out specific rules for data governance, including the fact that data are processed by them not based on individual consent, but on the legal basis that processing is necessary for pursuing a public interest.[51] *It is also clearly laid out that individuals may object to the processing of data in this way* (i.e. send a motivated request to stop the use of their data, which the agency may however still refuse), and the procedure how this can be done, and how the request will be evaluated.[52] Even in this case, the Finnish data governance architecture can be described as containing some of the underlying principles of data donation and data solidarity. In his study on the Finnish system, Tupasela underscored that their governance contains the principle of reciprocity and public good, rather than the element of voluntariness/act-of-giving, since citizens’ data is de facto always collected without them having to exercise a direct choice for this to happen.[53] More generally, Nordic systems of data collection and governance are considered – as a whole – a goldmine for public health. In fact, *their systems of data management is based on the prominence of solidarity over other ethico-legal principles such as autonomy*.[54]

France and the experience of the health data hub

In France there have also recently been developments that point at data governance structures resembling certain principles at the basis of the concepts of data donation and data solidarity. The most important one is the creation of the French Health Data Hub, “a public structure whose objective is to enable project coordinators to easily access non-nominative data hosted on a secure platform, in compliance with regulations and citizens' rights”.[55] This authority does not necessarily control data themselves, but rather acts (almost) as a one-stop-shop for identifying and then reusing for secondary research projects many of the data that are collected when individuals interact with the national health system. It does not access (or provide access) to anonymized information, but mainly to pseudonomysed data. Both private and public researchers can apply for access to the data, only *when they can demonstrate that the research project they want to conduct is in the public interest*. Indeed, it is explicitly said that data “will be accessible to project coordinators contributing to the public interest, following an approval process involving an independent committee (CESREES) and the National Commission for Data Protection and Liberties (CNIL).”[55]

Moreover, all projects that have been granted data access are also listed and publicly available, in order to help ensure transparency towards citizens.

The data that are managed by the Health Data Hub are collected in multiple ways at the origin, and not necessarily through explicit individual consent. However, patients can exercise through the agency a series of rights related to the control of their information (e.g. right to access data and – if they are incorrect – right to ask for the rectification of data). Another important element that connects this initiative to data donation and data solidarity is the fact that *the Health Data Hub has a mandate to keep society engaged*. In one leaflet describing this commitment, *they also draw directly from the vocabulary of donation, by comparing the act of providing health data for reasons of public interest to that of donating blood*.[56] Although the initiative is arguably organized around a top-down approach, it is actually better described as a combination of bottom-up and top-down. In fact, local data providers (i.e. the individual databases that connect to the Health Data Hub and allow reuse of their data through it) maintain some degree of control and specific data access policies. Indeed, also its catalogue of data is built up iteratively and through successive cooperation and establishment of good practices and not forcibly by decree.[57] For this reason, the governance model has been described as one of subsidiarity, where central structures and decision-making powers intervene only when tasks cannot be performed locally.[58]

Info-Box on the French Health Data Hub

The Health Data Hub is a new central point of contact for managing the secondary use of a good part of French health data.

It is responsible for managing requests for secondary use of data collected in the national health system, as well as associated data sources.

It offers as services that facilitate the journey in the French health data landscape for researchers.

It helps determine whether a request to access data for secondary research lies within the public interest. A dedicated page on their website specifies their understanding of public interest (which does NOT exclude private researchers, but excludes, for example, research aimed at promoting one product). Each access request (and the compliance to public interest) is evaluated by two committees, an ethical and data protection one.

For individual rights to their data, it helps to exercise their rights (such as require the right to access data, or rectify it), but this also depends on where the data are hosted.

Germany and its ongoing work on data donation

In Germany there has been for quite some time a discussion on whether and how to implement the concept of data donation. Indeed, the latter was famously mentioned in an influential report by the German Ethics Council (a federal institution providing advice on matters of bioethics broadly conceived for policymakers). The report – titled Big Data and Health and published in 2018[59] – suggested that the possibility to implement data donation as a legal concept should be explored. *Data donation was defined as a legal pathway to allow the processing of personal data with a broad consent for clinical and medical-related research without a precise purpose limitation.* Only a dissenting opinion in the report expressed the opinion that a data donation – if implemented – should still be bound to specific purposes. After this initial impulse by the Ethics Council, the ministry of health commissioned a long scientific report on how more precisely data donation could be implemented as a legal concept. This led to the publication of the report “Data donation – research need, ethical evaluation, legal, technological and organisational framework conditions”.[60] *The report included a large proposal on how data donation could be concretely operationalized and concluded with five main recommendations*:

1) Data donation should be organized so that it is separated from the clinical context. Citizens could then manage data donation during their everyday life, to avoid the pressure that a medical context can have on voluntariness.
2) A specific legal basis should be created for data donation, whereby the donation of health data happens automatically, but then citizens have an easy-to-exercise right to opt out.
3) Decisions on what donated data should be used for (in terms of secondary research project) should be determined by specific access committees.
4) A federal general law on the secondary use of data for research is essential for creating the necessary uniform framework conditions.
5) The implementation of data donation (both its successes and its challenges) should be monitored by a specific data donation advisory board.

Based on these reflections and on further reflections, there is one specific recent regulatory development that may correspond to a concrete implementation of data donation in practice. Indeed, as a report of the European Union covering various aspects of data governance in the member states noted, Germany is implementing “the Patient Data Protection Act, providing insured persons as of 2023 the option of making data stored in the electronic patient record available for research”.[28] *This pathway has also been defined by a report of the Bertelsmann Stiftung as a true legal implementation of data donation*.[61] A more recent (December 2023) press release described how this would work, including some significant developments (i.e. the decision to go for an opt-out solution). It was explained that a digital and interoperable digital patient dossier should be available for everyone starting from 2025 (likely similar to the Electronic Patient Dossier in Switzerland), and *that this would include the automatic donation of data for research with the possibilities of patients to opt-out from this process*.[62] This has also been explicitly confirmed in the specifically designed law for this aim, the “Health Data Utilisation Act” (Gesundheitsdatennutzungsgesetz).[63] This whole infrastructure and data governance system are currently in the making, together with a Health Research Data Center (Forschungsdatenzentrum Gesundheit) that *should be responsible for managing most matters related to the secondary use of data from health insurances and electronic patient files.*[64] Whether (and to what extent) the initiative will be successful is still under debate.[65–67] An important element to consider in this respect is also the availability and readiness of German residents to provide data through a newly established data donation system.[f]

Info-Box on the German Forschungsdatenzentrum

The Forschungsdatenzentrum is the German data centre – currently under construction – that will manage access to many health data (mainly collected as part of statutory health insurance) for secondary research purposes.

It will be responsible for managing access request for secondary use for research from different types of researches.

In regard to public interest, the law determines which purposes can be pursued when access is requested

For individual rights to their data, the health data is collected through a legal basis, so no consent or opt out are possible in general. If further data (e.g. from electronic patient dossier) is added in the future, possibilities to opt out will be explored.

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[f] On this topic, see e.g.[68] or [69]

The EU and data altruism

One of the most recent (and still work-in-progress) developments in the international context that can offer an example of how data donation and related concepts can be implanted comes from the European Union. Given the legislative competences that this has in field of supra-national importance (where the EU can pass legislation with direct applicability in the Member States), there have been many regulatory acts passed in the last few years and with direct relevance for data governance. One of the most recent is the Data Governance Act. It entered into force in 2022, but became applicable after a transition phase only very recently (September 2023).[70] Whilst the main aim of the legislation is "to increase trust in data sharing, strengthen mechanisms to increase data availability and overcome technical obstacles to the reuse of data" including in the health sector,[71] it also contains some specific rules on data altruism. The latter is defined as:

> "the voluntary sharing of data on the basis of the consent of data subjects to process personal data pertaining to them, or permissions of data holders to allow the use of their non-personal data without seeking or receiving a reward that goes beyond compensation related to the costs that they incur where they make their data available for objectives of general interest as provided for in national law, where applicable, such as healthcare, […] or scientific research purposes in the general interest"[70]

In this context, *the EU is thus in the process of creating what could be called an implementation of data donation (or a concept with the same underlying principles and purposes, i.e. data altruism) in the legal sense*. In fact, it is setting up a series of legislative rules that would permit to collect and use data directly through them, thus not using the reference to donation or similar concepts (e.g. altruism) only in a symbolic sense. The actual operationalization of data altruism is left primarily to the Member States, but there are also some indications at the EU level to guarantee uniformity. Based on them, data altruism seems to be supposed to operate in the following way.

Info-Box on Data Altruism Organizations

This is a specific type of non-profit organization which can be set up according to the Data Governance Act and its specific requirements.

Once created, they can act as data intermediary, by collecting data from individuals through the "data altruism" model.

With the data collected, they can then offer services to researchers, e.g. grant them access to the collected data for secondary research that respects the non-profit nature of the Data Altruism Organization.

They will also help to enforce individual rights (e.g. in case the person who has originally provided data through the "data altruism consent form") decides to withdraw it. How this will work in practice is difficult to estimate since – as of June 2024 – only one such organization has been created in the whole EU.

1) First, each individual Member State is supposed to set up Data altruism organizations. These must be non-profit organizations that fulfil a series of requirements set by the EU and aimed at guaranteeing transparency and citizens' trust.
2) Data altruism organizations need to have as main objective that of promoting general interest purposes by collecting individual data in the framework of data altruism.
3) Collection happens by the provision of data directly by individuals through a *European data altruism consent form*. In other words, the EU is tasked to design a homogeneous form whereby citizens will be allowed to give data to data altruism organizations for them to use exclusively for public interest purposes.

4) It is also envisaged that there should be a possibility for citizens to withdraw the provision of data they have made through the data altruism consent.[72]

As it is clearly evident, there are still many open questions about how the system of data altruism will actually work. Indeed, the whole architecture and data governance model constituted by data altruism is in-the-making, and – as of July 2024 – there is only one data altruism organization officially registered in the public database by the EU,[73] and there is no template for the European data altruism consent form. Moreover, it has been observed that "although the [Data Governance Act] aims to codify [i.e. turn it into an explicit legal concept] data altruism, there is little evidence as to whether the concept as proposed partly or fully aligns with how data altruism or similar concepts such as data donation have been previously conceptualized in the literature".[74,75] On top of that, also the role of consent is not clear in the data altruism model of the EU. Legal analysts have observed – for instance – that is not clear whether data altruism consent will be a new legal basis to reuse data, or if it is simply complementary to the consent requirements laid out by the General Data Protection Regulation (GDPR, the EU general law on personal data processing) in the EU. This calls into question amongst other things, whether such consent can be also broad/general or if it has to be tied to a specific research project. Non-Governmental Organizations have complained about the blurry data altruism mechanisms designed by the EU, and have claimed that:

> "The EU could have […] created a legal ground for data donations, the permissibility of which is disputed among data protection experts. It could at least have provided some legal certainty by defining "data donation". A possible definition could be: "Data donation is the permanent provision of data for context-specific information-gathering processing, without any direct incentive in return and without the donating party necessarily having any influence on the concrete use in the individual case."[76]

There have been *some hypotheses on why the EU decided to implement the new concept of data altruism rather than explicitly data donation*. Lalova-Spinks and colleagues argued that "the word [data donation] may have been deliberately avoided by the legislator, as it implies ownership transfer, whereas the fundamental right to personal data protection cannot be contracted away".[27] The Joint Action Towards the European Health Data Space (TEHDAS) – a EU funded initiative that "supports EU member states and the European Commission in building a European health data space by developing principles for the cross-border secondary use of health data"[77] – offers two different, but also contradictory explanations. In one report from 2022 on data altruism, *it repeatedly puts data altruism and data donation on the same level, basically suggesting that data altruism is simply the name given by the EU to a regulatory instrument which de facto corresponds to an implementation of data donation as a legal concept*.[78] In a later report on data altruism in 2023 it writes that "it should be noted that 'data donation' has different purposes and way of operating than data altruism",[79] but does not give any precise explanation as to why this is the case. Further developments can be expected, as TEHDAS was recently (May 2024) funded for a second mandate to continue investigate these issues.

4. The Swiss Context

After illustrating the historical development of the concept of data donation and its inherent unclarity and having presented how – despite the unclarities – there have been attempts at implementing data donation and its related concepts, we now turn to the Swiss context. More specifically, in this Chapter *we explore how the concept of data donation has already played a role in some attempts at implementing new data governance models in Switzerland*. This is important to illustrate that even in the Swiss context data donation has already had a concrete impact, and any future evolution of the concept will thus not develop in a vacuum. We then collocate Swiss initiatives related to data donation in the broader context of how health data governance for research has been recently developing in the country. Indeed, Switzerland has been deeply rethinking its health data strategy in the last few years, in order to keep up with digitalization. This need is evident from political initiatives on the topic,[2] roadmaps from the pharma sector,[80] infrastructural projects,[81] and also academic reflections.[82] We finally turn to giving overview of the empirical evidence available concerning the attitudes of Swiss residents towards the donation of data or the reuse of health data for research.

4.1 Data Donation in Switzerland

Some initiatives that rely on an understanding of the concept of data donation or that have adopted its (or similar) framing are also present in Switzerland. These, despite being arguably less advanced than the international initiatives presented above, show not only that *there is increasing attention for the operationalization of data donation directly in Switzerland*, but also that any future attempt to consider (or implement) data donation can learn from the first pioneering attempts that have been developed so far. In going through these examples, it is important to remember that they are merely attempts at putting into action data donation, a concept which – as we have shown in the previous chapters – is open to various types of interpretations due to the blurriness of many of its features. They are thus not to be considered as *prescriptive* of what any future operationalization of data donation should look like, but only as *descriptive* of the work that has been done on (and around) this concept in the most recent times in Switzerland at a practical level.

The data donation initiative by Risiko-Dialog

The first initiative consists in a project coordinated by the foundation Risiko-Dialog,[g] which – motivated by the Parliamentary postulate[3] this report also addresses – launched use-cases projects with diverse partners to try and operationalize data donation in Switzerland.[83] In brief, they wanted to show how a specific understanding of data donation could be implemented to conduct specific projects that had also to do with the field of public health. To contextualize their work, it is first important to understand that they applied data donation as a symbolic concept (see distinction above), and not as a legal-regulatory one. In other words, they used the existing regulatory framework which allows to collect and process personal data based on the consent of individuals, but framed the act of giving consent for data collection/reuse as part of their projects as a "data donation" aimed at serving the

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[g] https://www.risiko-dialog.ch/

general/public interest. Starting from this understanding of data donation, they then applied it in two use cases.

First use-case

The first use case was developed in collaboration with the University of Zürich and structured as follows.

a) The University built an online questionnaire where its affiliates (workers and students) could voluntarily provide some data about their health situation (e.g. vaccination status) and their movements (e.g. participation in university classes) to help manage the COVID-19 pandemic in 2021.[84] This provision of data for a ‘non-commercial purpose’ (i.e. fighting the pandemic) was framed as a “data donation”, although it was not – in strict terms – different from any other anonymous questionnaire aimed at researching matter of general interest.
b) As part of this, Risiko-dialog added into the questionnaire one specific element to investigate how data donation works. Half of the respondents from the sample received an invitation which framed the action of ‘filling in the questionnaire’ as an *act of sharing* of data for personal advantages; the other half received an invitation which framed the action of ‘filling in the questionnaire’ as an *act of donation* of data for societal and non-profit goals.

The *main finding of this part of the use-case was that the participation quota remained extremely low, as only 7% of the invited UZH affiliates replied and provided data* (2’447 out of 34’762), thereby also not providing enough data to see if the different framing had any effect. To investigate the reasons for this low level of participation, a further questionnaire was sent in March 2022, this time to investigate the general attitude towards data donation and potential motivators for or against it. 1’557 people provided a response to the full questionnaire and the main findings were:

a) 44% said they provided their data in the previous semester;
b) the majority said they did it for motives of general interest (49% to help with fighting the pandemic and 28% to help the UZH to create a safe working and learning environment).

This second survey was followed by another explorative survey where only 65 people participated, asking *what would help – in their view – to implement data donation* (defined as provision of data for a non-commercial purpose). The main findings were that participants should keep the right to ask for the deletion or erasure of their data and that data should be anonymous.

In general, *this case study shows that when data donation is applied in practice, participation remains very low* (thus signaling a difference between the declared willingness to donate and the actual act of donating – see Chapter 4.3 below). Moreover, the results indicate that *people want both to provide anonymous data and at the same time to retain the right to ask the erasure of such data, which shows a problematic misunderstanding*. Indeed, if data are truly anonymized, they are not related to any specific person anymore and it is thus impossible to guarantee the right to ask for their erasure. At the same time, this may show a fear that data could also be incorrectly anonymized, thus leaving the possibility of re-identification.

Second use-case

The second use-case by Risiko-Dialog was a collaboration with the City of Zürich as the latter wanted to obtain mobility data from citizens to improve traffic planning for the city. This goal is of public interest, as it allows to reach the climate goals (and thus also public health) of the community. This makes this use-case a good candidate for implementing the understanding of data donation as provision of data for common-good projects. It did not concern health-related data in the strict sense, but the project is still relevant to understand how the idea of data donation is conceived in Switzerland.

A collaboration was initiated with POSMO, a platform offering an app to collect data on mobility with the aims of:

1) collecting data on people's movement useful for the goal of improving mobility;
2) experimenting whether/how an effective communication campaign on the reasons behind (and the importance of) data donation would improve participation.

To test this, residents of the city were motivated to provide mobility data through the POSMO app with 4 differently designed campaign leaflets (in a digital form) disseminated between 2022 and 2023 through different social media and other online channels. *For the governance of the data collected through this initiative, a specific structure (including an ethics council) was designed*, in order to underline the non-profit and data-for-common-good character of the initiative. At the same time, it was declared that the business model of such initiative should be that of collecting data to provide them in an aggregated form to others for reuse (for common-interest goals) in exchange of a fee.

As part of this project, it was also demonstrated that an accurately designed information campaign can help to sustain data donation initiatives – but it must be noted that there are limitations to the study executed. Moreover, in a post-project questionnaire people were asked once again about general attitudes towards data donation and potential motivators for/against it. This produced some interesting results. There was general approval for data donation and societal benefits were put forward as main motivators. But even in this case there are substantial limitations to the findings, such as that only 48 people completed the whole questionnaire. In their final white paper,[83] Risiko-Dialog presented also some general data on mobility data collected as part of this initiative in data donation and shows their potential usefulness, and also how this was discussed with societal and political stakeholders in Zürich. They also highlighted how the most interesting analysis that one would be able to do through similar projects of data collection/reuse would require high-granularity of data. Granularity would, however, reducing the anonymity of the data itself, which is one important prerequisite for people to be convinced to donate their data.

The data donation lab

Another initiative that tried to implement data donation in the Swiss context has been kickstarted recently by the University of Zürich. As part of the Digital Society Initiative, a "Data Donation Lab" was created, which has the objectives to:

1) "Provide a platform for transdisciplinary knowledge aggregation and dissemination" and
2) "Provide an Infrastructure to Collect Data Donations".[85]

This lab has, however, *a specific understanding of data donation*. They define it as "person's consensual act of sharing (donating) data for research purposes", but – in terms of context and types of data – they mainly refer to digital traces automatically collected by the electronic devices that people use.[86] Moreover, just like the previous initiative, *they only refer to living/in-vivo donation and not the donation of (health) data of deceased people*. In this sense, they see data donation mainly as a way to leverage data that people generally collect by using smartphones or other wearables to then conduct research for the general interest. *They also subscribe, in other words, to the more symbolic conception of data donation, as in their case data would still be collected through the legal-basis of individual consent*, but specifically for reasons of common interest and in the frame of acts of altruism. In their implementation of data donation, they see citizens/individuals as the central components. The latter can, through the exercise of their legal rights (e.g. to obtain a copy of the data different online services collect about their behaviors), act as catalyst to retrieve a lot of data concerning them, to then put them at the researchers' disposal. This initiative is relatively new, as they had their founding meeting in July 2021, but set their activities in motion towards the end of 2022.[87] At the same time, they are making considerable steps to try and expand their outreach and their know-how, for example by:

1) having organized a data donation symposium in the second half of 2023 to explore various aspects (also ethical and legal ones) related to their conceptualization of data donation;
2) having planned, for the second half of 2024, the first Swiss Data Donation Day, which aims "to increase people's awareness of the possibility to donate their personal digital data to research and provide them the opportunity to participate in a project of their choice".[88]

Final considerations on Swiss initiatives around data donation

To summarize, in Switzerland some initiatives which have explicitly embraced the framing of data donation are already present, but they have not solved many of the questions that revolve around the issue of implementing data donation in a specific context.

The most important takeaways we can derive from them are:

1) the fact that *data donation is conceived as a symbolic concept* (see description above);
2) that its *main feature is the act of providing data for reuse in projects/aims of general/public interests*;
3) that individuals, as a catalyzer of the data they collect, are at the center, also in the sense that *their acts of data donation must be conscious and explicit* (i.e. not based on an automatic provision of data with the right to opt-out, but rather on the conscious giving of data after having been informed);
4) that *they are focused on specific sets of data*, either originally recorded by wearables or assessed through questionnaires, but not on data saved on other databases, or on 'all data' of a specific kind (e.g. all health-related data) generally conceived;
5) that *they do not consider posthumous data donation*, but only data donation by living persons;
6) that *they encounter the issue of balancing the desire to respect privacy concerns by anonymizing and the need to have granular data for analysis*;
7) that *they highlight a lot of unclarity in the public understanding of data donation*, given that all initiatives highlight the need of better communication and knowledge transfer with the community. The data collected as part of the first initiative also indicate peoples' desire to both have their data anonymous and the possibility to ask for their erasure (which are diametrically incompatible requests).

These findings also match with some of those which are revealed by scientific studies on people's attitudes towards data donation, as listed in Chapter 4.3 below. In any case, *they are to be considered as preliminary, since the initiatives we reviewed are relatively new, exploratory, and pioneering in the field*. It is to be expected that they will continue in the future and new developments need to be followed. Moreover, *it is important to keep observing how the frame of data donation is also used in specific instances by other initiatives that are not built around data donation in their entirety*. For example, the project of Corona-Science has been collecting data through the usual legal basis of consent, but it has also – in specific instances – framed the issue of providing data to them as "making a donation of data" (see their page in the French language).[89] At the same time, the term data donation was also sometimes used in the studies about public views and attitudes on the provision of data for secondary research purposes that we analyze in Chapter 4.3.

4.2 The broader context

The Swiss initiatives adopting explicitly the framing of data donation listed above do not happen in a vacuum. On the contrary, they were developed within a broader context of rapid developments happening in data governance. Data governance can be understood as the sum of "rules and policies on the exchange [and re-use] of data; people and organizational body which make and operationalize the rules; and concrete processes that people follow to process the data".[90] It is important to thus contextualize the initiatives presented above by offering a short overview of the most recent developments in the evolution of Swiss health data governance that matter for the topic of data donation. This is ever more relevant in order to make sure that there is some alignment and possibly even coordination between the direction towards which data donation initiatives and other important projects in the field of data governance (e.g. DigiSanté[91]) are moving.

One set of important developments for the context of data donation has been happening with respect to two projects aimed at favoring the build-up of important data sources: Electronic Patient Dossier (EPD) and cantonal cancer registries.

The EPD is a project coordinated (and regulated) federally, but with the concrete involvement of cantons and private data platforms. It is aimed at building an interoperable data ecosystem where citizens can open a personal health record in which they save several types of data that they produce in their various contacts with different healthcare providers (e.g. results of examinations, discharge letters from hospitals etc.). Relevant for data donation in regard to the EPD, is a recent proposal to change the EPD law in a way that citizens should in the future be allowed to indicate their consent for allowing access to their EPD data and reuse for research.[92] This means that the possibility to 'donate' (symbolically) EPD data for research may be available in the next future.

On the other side, cantonal cancer registries are databases managed at a cantonal level but federally regulated, which are legally obliged to collect structured data on all cancer cases in the territory of interest.[93] Data in these registries can – upon certain conditions – also be used for secondary public health research and monitoring. Until recently, data could be collected only if the diagnosing physicians had conducted (and documented) a consultation, where they would provide single patients details on how to opt-out from data registration. Now, on the contrary, it is possible for cancer registries to record data even if the diagnosing physician does not transmit all documents certifying this consultation took place on a specific date.[94] Thus, more data will be available for reuse, symbolically fostering the idea that cancer-related data are to be donated to the registries for the benefit of the community (i.e. some form of data solidarity).

One further relevant development is the recent entry into force of the new Federal law on data protection.[95] This is a general law that regulates the processing of data by federal institutions and private persons (e.g. including legal private persons such as pharma companies) and interacts with cantonal data protection laws (which regulate the processing of data by cantonal authorities, including cantonal universities). The new law maintains many principles of the old federal law on data protection, but also introduces some adaptations. A thorough analysis of this piece of legislation is available elsewhere.[96] Two main things are important to notice here. First, this law is of general nature, meaning that if a more specific law on the processing of data is available, the latter will take precedence. For example, when it comes to the secondary use of personal health-related data for research, the rules that are contained in the Human Research Act (HRA) will have precedence, given that this is a *lex specialis* for the human research field.[97] Second, it should nevertheless be noted that the new federal law on data protection contains further some rules regarding the processing of health data that could be relevant for the context of data donation. Specifically, art. 31 para 2 letter e defines that in case data are processed for non-personal reasons (e.g. for research), consent is not necessarily required, as long as the responsible data holder gives the data out to third parties without individual people being recognizable, or (when this is not possible) by ensuring that third parties will only use data for non-personal reasons. An individual estimation of the risks has to be made in any case.

At the legislative level, it is also important to mention that the ordinances detailing the HRA and regulating various aspects of medical research that it entails (also covering projects using health data) are currently being revised.[98] For example, the revision of the Human Research Ordinance (HRO) is in process,[99] which entails some elements that are relevant for the context of data donation. These include the possibility of explicitly allowing the collection of informed consent in an electronic form. The proposed changes to the HRO article 8b would state in a clear way that – in the context of research – it is possible to get informed consent in an electronic form, as long as certain conditions are satisfied, such as that the consent is given through a procedure that allows the unequivocal identification of the person and that it is protected from accidental modifications according to current technical standards.

At a political level, it must be reminded that the parliamentary motion 22.3890 has called for the creation of a new framework law regulating specifically the secondary use of data, including also matters of health data and research.[100] The motion was approved by the Council of States in December 2022 and the National Council in June 2023 and it is under the responsibility of the Federal Department of Justice and Police.[101] It is to be expected that the administrative and legislative work related to this initiative will also touch on relevant aspects concerning data donation and the topic of health data reuse in research. In this respect, it is also noteworthy to mention that there have also been initiatives by private stakeholders and others, which have pushed for better framework conditions for the secondary use of data and – amongst other things – for considering the establishment of a health data space in Switzerland.[102]

Other relevant activities in the broader realm of data governance that bear on the context of data donation are:

1) the work of the Swiss Personalized Health Network (SPHN) in respect to the reuse of clinical data;
2) the ongoing activities aimed at (re)defining the scope and application of General Consent in Switzerland with respect to the secondary use of data for research.

The work of the SPHN is pertinent since this nationwide initiative sits at the crossroad between the setup of concrete data flows between different institutions (e.g. university hospitals and researchers) and the settlement of appropriate governance structures. One of their achievements relatable to the context of data donation is the fact that they created a series of templates for legal agreements concerning the exchange of data (e.g. for reuse for secondary research), which help also to regulations for the cases where individuals withdraw consent.[103] On the other side, there are also activities going on (re)defining the application and alignment of the conditions to use General Consent, coordinated by stakeholders like Unimedsuisse and the Swiss Clinical Trial Organization. A publication coordinated by the latter has also observed that in some cantons the number of projects that have been approved and used general consent has increased, reducing at the same time the number of approved projects that did not collect consent (relying on art. 34 HRA).[39]

Lastly, it is essential to never forget the different non-governmental initiatives that have been launched recently to influence Swiss data governance in the healthcare sector, and that thus concern the field of data donation. One of this is aimed at influencing from a citizen-driven and participative perspective the set-up of a swiss health data space, in order to keep individuals at the center of this development.[104] Or else CH++ is another very active organization in the field of data governance, which is also involved in the health data field as evident by their publications (e.g. on the EPD and the potential new rules for people to give or withdraw consent).[105] Finally, Switzerland is also the home of one of the first international examples of data cooperatives, named Midata.[106] This is a citizen-science initiative structured as a cooperative that aims at giving people more control over their health data, by giving them a chance to upload them in a specific account, which can then be provided for external researchers to conduct reuse projects on it. In the past, this cooperative has also been associated loosely to the concept of data donation.[107]

4.3 The readiness for data donation

Whether data donation is implemented as a legal concept to offer another ground to collect/process health related data or a symbolic one to accompany and reinvigorate initiatives aimed at compiling medical information, *one necessary prerequisite for it to function is people's readiness to provide their data for reuse.* This is the reason why the attitudes of the broader population or of specific groups (e.g. patients) are measured in many national and international context. A positive predisposition of individuals towards data reuse is necessary not only when the ethico-legal governance requires them to actively do something to provide data, but also when the regulatory framework establishes that their data are automatically collected for reuse. In the first case, people's readiness is crucial because, if they are uninterested in providing data, they are less likely to perform the required action (e.g. providing consent) for the collection and reuse of data. In the second case, a positive attitude is likewise essential, but in this case to ensure that the policies catering for an automatically collection of data and reuse are not opposed and eventually boycotted (e.g. by opting out in large numbers). For these reasons, in this chapter we give an overview and critical analysis of the available evidence concerning Swiss attitudes towards data donation broadly conceived, i.e. their attitudes towards the idea of providing data for secondary research purposes of public interest. These studies are summarized in Table 4 below, and explored more in detail in the paragraphs following.

Table 4. Overview of research on attitudes towards data sharing in the Swiss population

	Central research question	**Essential methodological features**	**Sample information**	**Main findings of relevance for this report**
Mählmann[108]	Are Swiss older citizens willing to donate genetic data for scientific research?	Qualitative semi-structured interviews. Not clear if the term “data donation” was present directly in the questions.	40 senior citizens from the Zürich area	-People are willing to donate for research that benefits society (altruistic motivations) -Donations of (genetic) health data should be like organ or blood donation: gratuitous and altruistic -There is still a need of data protection and transparency on data usage
Rivas Velarde[109]	Do the recipients (data re-users) or the conditions of donating data influence people’s attitudes towards health data sharing?	Mixed-method study with both close-ended and open-ended questions. The questions mentioned explicitly the term “data donation”.	73 individuals from the Geneva area	- the recipients (i.e. who is the data re-user) influence willingness to donate (high willingness for hospitals, low for private companies). - opposition by participants towards the idea of donating health data to obtain a personal profit - approval of the idea of donating data for public good initiatives
Brall[110]	What are the attitudes in the Swiss general population for data reuse in personalised health research?	Survey with structured (i.e. mostly close-ended) questions. The questions did NOT explicitly mention “data donation”, but the researchers used the term nevertheless to present their results.	More than 5000 respondents from all language regions	-53% of respondents indicated willingness to donate health data for secondary health research -Type of data influences the willingness (e.g. higher for health data collected through questionnaires and lower for health data collected in apps) - fears (e.g. discrimination) related to donating data are widespread
Brall[111]	What are the opinions of the general Swiss population towards health data governance?	Same methods as Brall 2021 (previous line), different portion of results were presented	Same sample as Brall 2021 (previous line).	- only 17.7% of respondents said they would prefer to be consulted only once (when health data are collected) about their general consent to donate their health-related data for further use - doctors are seen as the most trusted party to control health data, whereas pharma companies are less trusted - many respondents want their data to be anonymous BUT also keep control → lack of understanding of anonymisation
Stübi[112]	Is the Swiss general public ready to donate (health) data in a public health emergency?	Quantitative study based on a structured survey. The term “data donation” was used directly in the questions.	1558 respondents from all over Switzerland	- 60% of respondents are willing to donate data for socially relevant aims - such data should be managed by federal authorities (53.8%) or by research institutions (32.6%) - the type of data respondents would be willing to donate depends on the purpose of (re)use

Pletscher[113]	Would Swiss people be ready to share anonymised routinely collected clinical health data?	Quantitative study based on a cross sectional survey. The term “data donation” was NOT used directly, participants were asked about willingness to share data.	1006 respondents from German and French speaking Switzerland and 225 patients suffering from chronic diseases	- more than 70% of respondents are willing to share anonymised health data. - the main motivators knowing that sharing may help others and knowing that data protection measures are present - Respondents trusted mostly public institutions for data sharing (hospital, universities and Federal Office of Public Health) -56% of respondents desire to be better informed about how health data are used in research
Deruelle[114]	Is people’s willingness to store/share data in specific databases influenced by whether health data are described as common or private good?	Quantitative study including survey questions mixed with experimental design. The term “data donation” was NOT used directly, participants were asked about willingness to store/share data.	1000 respondents from the general population (German and French speaking Switzerland)	- if the act of recording data and storing/sharing them in databases is framed as a “common good” activity (data as common good to be reused for public health), respondents were LESS willing to store/share health information - if the act of recording data and storing/sharing them in databases is framed as a “private” activity (data as private good, to be reused only if the health of the individual they belong to is improved), respondents were MORE willing to store/share health information
Golder[115]	Would respondents agree to share data from the Electronic Patient Dossier with researchers after consent?	Quantitative study with structured survey. The term “data donation” was NOT used directly, participants were asked about willingness to share data.	Almost 200 respondents from the different language regions.	- 51% of respondents agreed or rather agreed - 21% disagreed or rather disagreed - 21% mentioned that it would depend -7% did not reply

One of the first studies to explore Swiss views towards the provision of data is a qualitative project investigating the willingness of donating genetic data for scientific research.[108] Semi-structured interviews were conducted with 40 senior citizens. The majority of participants were willing to donate data, motivated mainly by altruistic reasons and a desire to contribute to the wellbeing of society. Many participants made in their interviews a direct comparison between data donations and other forms of donations. For example, a participant said to be ready to donate data just like he would be willing to donate organs. Another argued for the principle of gratuity in data donation, since also blood donations are gratuitous. Despite a generally positive attitude towards data donation, there were, however, also many discussions about the need for accurate data protection and more transparency regarding data (re)use. The study was of a qualitative nature, only focused on genetic data, and had a non-representative sample of the general Swiss population. It nevertheless offers some initial findings that concern the readiness to donate genetic data.

Another recent study explored similar questions with a mixed-method approach (i.e. involving both survey-style closed questions and qualitative open-ended approaches).[109] The authors recruited 73 participants in the area of Geneva. They then involved them in interactive sessions, which provided information material on issues related to health data collection and (re)use. The objective was to then invite them “to reflect on social and research actors, types of data, and desired levels of control while sharing different types of data with different actors.” In the quantitative part of the study, participants were asked to express their opinion towards a series of statement, which included directly the specific framing of “data donation”.

More specifically, they were invited to consider statements such as “I would donate my data *to do disease research*”, or “I would donate my data to do disease research, *if I can withdraw at any point*” or “I will donate my data *to making money*” or “I will support *banning donating data for profit*”. For each of these statements, participants could indicate their agreement or disagreement also depending on a further variable, i.e. the recipient of data donation (e.g. hospital vs private companies). Agreements varied a lot depending both on the purposes/conditions of data donation (e.g. participants’ agreement was much higher for data donations that could be withdrawn) and the recipient (e.g. public hospitals and other public authorities generally scored higher, whereas much fewer participants agreed with statements about data donation toward pharma or other private companies). Interestingly, there was also a generally high agreement to the idea of banning donation for profit, suggesting that participants do not approve of the idea of donating data, whilst at the same time generating private gains. This finding was also somehow confirmed by the qualitative part of the study, in which researchers collected verbal statements from the 73 participants about the different scenarios of data donation that they evaluated. Many of these verbal statements (which were recorded, transcribed, and then analyzed qualitatively) indicated that respondents associated the idea of data donation to the purpose of maximizing public good and not private profit. In sum, this explorative mixed-method study gave some preliminary evidence regarding the readiness of Swiss people to donate data, in particular by showing that this is influenced by both the purpose/condition of the donation, and its recipients. However, it also had the limitation of a very small and non-representative sample.

The first study with a bigger sample and a quantitative design was carried out by Brall and colleagues, who collected data on peoples’ attitudes to providing data for personalized research, leading to two publications [110,111]. This was a large questionnaire project with more than 5000 valid responses and a representative population (from the German, French and Italian speaking parts of Switzerland), which used the frame of “data donation” to investigate peoples’ preferences. To be more precise, the term “data donation” was however not reported explicitly in the items of the questionnaire (which used more general phrases such as “would you like to make data available if…”), but it was explicitly used by authors of the study when reporting their results. In the first publication based on this study,[110] 53.6% of participants indicated their willingness to donate data in the context of research on personalized health. It was shown that willingness to donate data is “higher in younger, higher educated, non-religious respondents with a background in the health sector”. It also revealed that people’s preferences would change depending on the type of data (e.g. donating health data from questionnaires, those derived from blood or biological samples was preferred as opposed to donating data collected through apps). Findings also indicated that participants possess some fears related to donating data, (e.g. “potential discrimination, confidentiality breaches, and misuse of data for commercial or marketing purposes”). This shows that more engagement work is needed with the wider public to address such existing fears. In the second publication from this survey study,[111] results concerning people’s preferences with respect to the conditions upon which they would donate their data were explored. Important insights include: 1) the fact that many respondents (39%) wished to be re-contacted for each new study that would be initiated with the data they donate, or that this would depend on the project type (29.4%), whereas only 17.7% preferred to be asked only once when data is initially collected; 2) a great majority wished for data to be donated in and stored anonymously (52%) or in coded form (43.4%); and 3) most respondents said they would desire to personally own their data, and indicated their doctors and researchers at universities as the most trusted actors to protect their data. There is thus a tension between the fact that ‘anonymized data’ was the preferred category of data to donate, but many people did – at the same time – desire to be re-contacted each time their donated data would be used for a new project (something which is impossible if the data are anonymized). Other relevant results concern the fact that many (56.9%) did not consider financial compensation as an important motivator to donate data. Responses for this study were collected before the COVID-19 pandemic, and one of the limitations is thus that the effect of the pandemic (if any) on peoples’ perceptions is unknown.

A consortium involving the foundation Risiko-Dialog, the University of Zürich and the Swiss Data Alliance conducted the first large quantitative study on these issues after the break-out of the COVID-19 pandemic.[112] This study was also used as preliminary evidence to launch the data donation initiative described above in Chapter 4.1. Funded by the Mercator Foundation Switzerland, authors ran a survey from June to August 2020 to investigate whether and to what extent the Swiss population is ready to donate their data (including health related ones) in a situation of (public health) emergency. This specific condition was placed as the study was conducted in the context of the COVID-19 crisis, which showed how large amount of citizen-provided data (e.g. regarding infection and geolocation) can be useful to tackle emergencies. The survey was completed by 1558 participants from all over Switzerland, thus achieving both a considerable number of respondents as well as a good representativeness (e.g. regarding age, gender, education level, and residence). When asked for their general attitude towards the idea of donating data for socially relevant aims, 60% said they would be willing or rather willing to donate, 27% were unwilling or rather unwilling and 13% were undecided. They were also asked whether they would prefer a direct donation (where citizens would decide and a platform only act as intermediary) or an indirect one, with 59.7% opting for the former. When interrogated about who should manage such a platform, most preferences went to the federal authorities (53.8%) followed by research institutions 32.6%, whereas private sector companies (3.0%) and NGOs (7.1%) were considered rather unsuitable. The survey also revealed that the type of data people would be willing to donate depends on the reason/purpose why donation is required. For example, if the purpose is that of fighting of an influenza epidemic, then health data are what people are willing to donate.

Another large survey study on the willingness of Swiss people to provide data for secondary research was conducted by Pletscher and colleagues[113] and published in 2022. This survey is particular in that it focused explicitly on the context of secondary use (i.e. people were asked if they would make their already-collected data – e.g. in hospital record – available for further analysis by third parties). The study had a cross-sectional design and included two populations: a representative random sample (n = 1006) of the Swiss public (excluding however the Italian speaking part of the country) interviewed by phone in September/October 2020; an additional population of people with chronic disease (n = 225) survey through an online panel. When asked if they would share their anonymized health data for medical research, 71% of the general population and 81% of the chronic disease group signaled their willingness. Respondents were also asked for the main motivations that would convince them to share data in this way and the main hurdles. Motivators were mainly altruistic (e.g. 86%[h] said that they would donate data if they knew these would lead to better treatment for others) and control-related (e.g. 85% said that the implementation of data protection measures would drive them to donate), whereas direct financial compensation was not a driver (only 9% of the general population mentioned it). The main hurdles included “concerns

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[h] This and following percentages concern the sample from the general population.

about privacy" (74%), and "potential identification despite anonymization" (68%), highlighting the importance that data protection and data privacy play. There were two other findings of note: 1) people trusted mostly public institutions (hospital, universities and the Federal Office of Public Health) for handling their anonymized health data; 2) a majority (56%) of the sample expressed their desire to be better informed about how health data is used in research and saw mainly government bodies in charge of this task. In sum, this post-COVID-19 survey reveals high level of willingness to share anonymized health data for research, and confirms that data-privacy concerns are a core issue.

Deruelle and colleagues[114] performed another quantitative study on the attitude of the general population regarding the topic of recording and then storing/sharing health data on specific databases. In this case, the authors utilized a particular experimental design. They did not asked directly people whether they would be willing to record and share/donate personal data. Rather, they first asked individuals whether they would be willing to record their own health data through wearables/apps and genetic tests. Then, they asked whether they would be willing to store/share such data on databases, depending on two different frames: one based on the concept of data as private good, the other on the idea of data as common good. More specifically, they recruited 1000 participants in March 2020 and divided them into two homogeneous sub-samples of 500 each. Both sub-samples were first asked if they would use different technologies (e.g. genetic test or health apps) which allow to self-collect health data. Afterwards, one sub-sample received a specifically designed vignette to frame data as a common good and thus stored/shared within public databases. The other sub-sample received a different vignette to frame data as a private good and thus often stored on private data-safes or personal chips. The objective of providing different vignettes was to see whether being exposed to a different "framing" (data as common good vs data as private good) would encourage or discourage people to share their data for reuse. Results showed that people who received the "common good" framing became less likely to store/share health data as compared to those who received the "private good" one. Therefore, this experimental study produces evidence contrary to the previous surveys, which indicated that altruistic reasons (i.e. for the common good) were acting as motivators for sharing data for reuse.

Another project to consider when reflecting on the readiness of the Swiss population to donate data is the yearly Swiss eHealth Barometer, a study which analyses the attitudes of the Swiss population towards various aspects of digital health. In the 2023 edition (data collected between the end of 2022 and 2023 per post or online),[115] almost 2000 respondents from the different language regions of Switzerland were surveyed. One question regarded the agreement of people for making data saved in the electronic patient dossier potentially available to third parties for reuse for research purposes. Here 51% of the respondents agreed and 21% disagreed (21% mentioned it depends and 7% did not reply). Although these results are tied to the specific context of the patient dossier, they are still useful to gather some knowledge after the peak of the COVID-19 pandemic had past, showing that views remain quite divided.

The main insights from all the empirical research listed above are summarized in Table 5 below.

Table 5. Main takeaways from research on the Swiss population attitudes towards sharing data

Main insights from empirical research on Swiss public attitudes to data sharing for research
• There are both qualitative and quantitative studies regarding Swiss public attitudes towards sharing/donating data. • Most studies did not investigate the term/concept of “data donation” directly, but rather asked individuals what they think about providing their data for secondary research uses. • Studies indicate generally a positive attitude in a majority of the population towards the idea of giving data for secondary research uses, but: → Declaring the intention to share data does not correspond to actually sharing data → Individuals often pose conditions to their attitude towards sharing data for reuse (e.g. depending on who keeps them and/or access them for secondary research) → Studies have different designs and different framing of questions • Studies also show a high sensibility towards data protection measures. • Research also indicates poor understanding of certain issues (e.g. anonymization vs pseudonymization) and the desire to be more informed about which exact secondary research is done with data. • Most studies indicate that people want to share/donate data for altruistic and public goals, but the only experimental study showed that framing data as a ‘public good’ actually leads to a more negative attitude towards storing/sharing data.

5. Reflecting on the potential impact of data donation

After having investigated the creation and evolution of data donation as a concept, having analyzed how it was implemented in different international environments, and having contextualized data donation for the Swiss situation, we now turn to reflecting on the potential impact that data donation has in the future of Swiss data governance. The following considerations are based on the synthesis and analysis of available evidence concerning the concept of data donation and its implementations that we illustrated so far. They stem from a reflection on data donation from the point of view of ethics and data policy, but also touch on elements that concern the regulation of data processing more general. In so doing, we provide further material to feed into the broader discussion about the feasibility of implementing data donation in the Swiss context, and thus contribute to the discussion that the Postulat 20.3700[3] at the basis of this report initiated.

What would (health) data donation represent in the evolution of the Swiss health data governance framework?

Based on the review of the origin of the concept of data donation, it appears clear that this is *still surrounded by a great degree of uncertainty*. Not only does it NOT have a uniform definition, but some of its basic features are also unsettled. As an example, it is still hugely debated whether data donation should simply refer to the transfer of data after death (posthumous data donation) or if it is somehow applicable to the transfer of data between living individuals. Or else, it is not clear whether a donation of data should be withdrawable, or if it is definitive.

One element stands clear though. The idea behind data donation is that of developing a new data governance instrument to allow the reuse of data by researchers with *the purpose of conducting projects that serve the public good*, thus characterizing the act of giving data as a charitable/altruistic one. In other words, developing data donation is considered a way to redesign the balance between respect for autonomy of data subjects and the need for more data in the biomedical research field. To do so, data donation purports to leverage the values of solidarity/altruism. *Just like the call for blood donation is a call to provide biological material for the common good of society, the call for data donation is grounded on the same type of motivations, i.e. providing data for the common good of conducting research in the public interest.* It thus offers a slightly different conceptualization of the exchange of data as compared to the concept of data sharing. *Whilst data sharing is based on an idea of mutual advantage but also retainment of control (if I share something, it is still also somehow mine), donation is certainly also based on expectations, but of a different kind: namely, that data will be used for the public good.*

From this perspective, data donation may fit in well with the current development of the Swiss health data governance framework. Indeed, we have been witnessing some first steps to adapt a data governance system that was until recently based on individual autonomy,[90] to one that tries to accommodates more and more societal and collective needs. Indeed, in Chapter 4.2 we have underscored that in some crucial data infrastructures (e.g. Electronic Patient Dossier and cantonal cancer registries) more research-friendly solutions of data governance have started to develop. Therefore, *data donation could accompany this evolution towards a different structuring of health data governance, where individual choice* *and control remain important, but other interests* (such as the public interest in a better use of health data for high-quality and efficient healthcare) *are given a more central role*.

Data donation could represent an important piece of the puzzle for two reasons. First, recent studies with experts from the biomedical research and health policy field clearly show that the regulatory and data governance framework is still in need of adaptation. This adaptation relates especially to the role of individual people and the outreach of consent.[82,116,117] Second, it is clear that there are some concrete data governance loopholes that create problems for research for the common good. For example, a recent study on the Swiss amyloidosis registry,[118] which collects important data and performs research on this rare set of diseases, *highlighted that researchers encountered many problems in including and analyzing data from deceased patients, due to ethico-legal restrictions*. The Swiss National Registry for Primary Immunodeficiencies also *reported difficulties in dealing with the current data governance framework based on patient consent, since also this registry includes both data of people being alive and also deceased people*.[119] In a recent publication about a Swiss forensic pathology biobank collecting both biological material and data from deceased people,[120] *the ethico-legal complexities related to the handling of medical information after death have been outlined*. Hence, this realm (i.e. the governance of data from deceased people) is a clear case where the implementation of (post-mortem) data donation could certainly help. And the same holds true for the reuse of data from living people.

What are the options available to implement data donation?

As clarified in Chapter 3, some implementations of data donation and related concepts exist, but they are very heterogeneous in features and scope. Hence, *there is NOT one single model that Switzerland could try to translate in its own national context, but rather many models that have developed differently, based also on the data infrastructures and policy initiatives of their own (inter)national environments*.

At a preliminary level, it would be preferable for Switzerland to decide whether data donation should be implemented as symbolic concept or a legal one. If implemented as a symbolic concept, then it would only be necessary to frame as ‘data donation’ the act of providing data in various contexts (e.g. Electronic Patient Dossier, or medical registries) where then the actual legal basis for the processing of data would remain a different one (e.g. informed consent, or general consent). This would roughly correspond to that what the few Swiss initiatives which mentioned data donation (see Chapter 4.1) have already been doing. The one by Risiko-Dialog simply framed as ‘data donation’ the act of collecting data for reuse (about movement and health status through questionnaires, or data about mobility through an app), albeit their practices actually consisted in the collection of data through specific consent, and they could have worked from a legal point of view without any reference to donation. If data donation is implemented in this way (i.e. symbolically as a ‘frame’), the advantages would include (as discussed in Chapter 3.1) that no legal adaptation would be needed, and – at practical level – that using the vocabulary of donation would have a positive evocative power that may motivate more people to provide their data.

The other option would be to implement data donation as a legal concept. Considering this possibility in greater details would require a specific legal analysis, that this report is not designed to provide (as it is not a *Rechtsgutachten*). From an ethical and data policy point of view, we can underscore that an implementation of this kind would require *legislative changes. These would have to provide a specific definition and boundaries of what data donation constitutes*. Ethically, the main requirement would be that data donation should only be permitted for the provision of data for secondary research purposes of public interest, to honor the charitable and benevolent feature that is entrenched in the concept of data donation itself. Moreover, a legal implementation would have to resemble something close to what the EU is doing with the related concept of data altruism. Indeed, they have implemented specific legal rules that say what data altruism is, with an explicit definition, and the design of specific institutions that will be in charge of supervising the concrete implementation (i.e. the data altruism organizations). Needless to say, also a legal implementation will have advantages and disadvantages, the latter including that of uncertainty about effectivity. This is shown by the case of the legal implementation of data altruism described above. *Indeed, how well the EU data altruism legal concept will function remains an open question, since it has just been introduced in the law, and the setup of the whole system is still work in progress*. Thus, it is important for Switzerland to closely monitor these developments to see how they operate, rather than draw hasty conclusions at this very preliminary stage.

Another important choice to make for the implementation concerns the scope of data donation. More specifically, *it would be important to determine whether this concept should be applied to both the reuse of data from living individual and post-mortem donation, or if it should cover only the latter*. At the European level (i.e. outside Switzerland) and especially in the ethico-legal community (see also Chapter 2.1), there seems to be a *preference that the term data donation should only be used for post-mortem medical data donation*. On the contrary, however, the first initiatives related to data donation in Switzerland have used it in the context of the provision of data by living people, whilst outside Switzerland there is a preference to speak about data altruism or data sharing in those cases. In comparing data donation and the new EU data altruism model, Ferrè[121] observed that:

> “while data altruism has many points of contact with data donation, it differs from it primarily because it concerns the sharing of data of people who are still alive, allows for the revocation of consent, and ultimately stands simply as a new model of consent to the processing and reuse of personal data, moving away even through the choice of a different name from a proprietary view of data.”

In Switzerland, *there should be a discussion on whether to align with these ideas, or if data donation should be used more broadly for both post-mortem and living donation*. This discussion would then have to include a precise definition of other important elements (e.g. whether a donation of data can be revoked). Importantly, it would also need to discuss how to protect the interest of people who donated data to be informed (or not informed) in case research reveals important finding for them personally. In Table 6, the different implementation possibilities are summarized, with also the pros and cons they entail.

Table 6. Potential policy implementations of data donation in Switzerland

	Implementing data donation as symbolic concept	**Implementing data donation as legal concept (in-vivo)**	**Implementing legal donation as a legal concept (posthumous)**
General idea	Health data continues to be collected and re-used for research according to existing guidelines, but the collection/reuse is increasingly framed as a “donation”, as an “altruistic	A new legal basis for collecting and reusing health data for secondary research uses in the public interest is created. Through this new legal basis, individuals can choose to donate health data to a specific organization, so that it can be	A new legal basis specifically addressing the posthumous use of health data is created. This would clarify explicitly (thus addressing a partial legal vacuum) that the secondary use of health data from

	act" for the public good. The objective would be to foster public acceptance of health data collection and reuse.	reused for secondary research with less barriers.	deceased people for research is allowed. A further requirement would need that research satisfies a public interest.
Interaction with existing legal framework & concepts	The legal mechanisms for collection and reuse of data remain the same. Data is collected through consent or other legal bases (e.g. a specific legal obligation). The reuse for research also remains based on current rules (e.g. HRA art. 32-34).	The new data donation would be added to (or even replace) existing legal mechanisms. Option 1: It could be constructed to require explicit (broad) consent, which then can be retracted only prospectively (i.e. if data has been used in the meantime for some project, that past use remains legitimate). Option 2: Alternatively, it can be constructed to require only a prospective opt-out (i.e. data can be reused for public interest research, unless the individual has explicitly disagreed).	There would not be specific interaction with existing legal norms, since current legislation covers the reuse of data of living individual. The posthumous data donation scheme would be based on the possibility to reuse health data after death in a pseudonymized or anonymized way, unless the person has explicitly communicated an opt-out directly to the data source.
Role of National Data Coordination Center[2]	It could help with coordinating different data sources, and also with promoting the idea that collecting/reusing data should be interpreted as a donation.	It would help manage the new legal concept of data donation. It would help individual databases to register what data they can make available for secondary use based on data donation. It could also help to determine if a specific request for a secondary research project falls within the notion of public interest.	It could help to coordinate the secondary research with health data of deceased people from different data sources, as well as help them define which types of research meet the public interest requirement, and thus can proceed.
Advantages/ Gains	No change in the law is needed. Framing data collection/re-use as an act of donation, may help boost the public support for health data usage.	It may facilitate the reuse of specific sets of data (e.g. applied to data from statutory health insurance). It would give a secure legal ground for data reuse.	It would cover a partial legal vacuum, since nowadays the reuse of health data from deceased people is sometimes dependent on the decision of research ethics committees on the individual research project.
Disadvantages/ Challenges	Using the term of donation only symbolically can create confusion in the public. Moreover, the same ethico-legal issues currently present for data reuse would not be systematically addressed.	A change in the law is needed. Moreover, the exact relationship between the newly created data donation and other legal mechanisms for reusing data would need to be clarified.	Standing alone, it would not remove the obstacles concerning the reuse of data from living individuals.

As is evident in Table 6, each implementation would also require to think about the role that a National Data Coordination Centre could have in that respect. The role of similar agencies in other countries has been described in Chapter 3.2. The most advanced examples are those of the Nordic countries (Denmark and Finland), whose centers manage many aspects related to the secondary processing of health data for research. However, these countries also have a very different setup in terms of basic health data infrastructure (e.g. National Health Systems, some centralized databases). Therefore, it is important to look also at the examples of France and Germany, where the national data centres operate rather as coordination and knowledge centres, that help harmonise different stakeholders and their databases.

How would the implementation of data donation in Switzerland interact with existing health data governance concepts?

Together with clarifying issues related to the implementation of data donation itself, it is necessary to consider its interaction with other established concepts in Swiss health data governance. In this respect, *the most important clarification would have to be done with the existing concepts of informed (specific) consent and general consent*. Both of these are legal bases that can be used to justify the (secondary) processing of data for research purposes. Whilst informed (specific) consent consists in the provision of a specific permission for each new reuse of data, general consent is given once to cover multiple reuses of data for any yet unknown future research project within the limits of the HRA. The second is currently being developed at several hospitals to try and implement it through a harmonized consent form. In respect to data donation, *the main point of needed clarification includes a discussion on whether data donation would be complimentary/supplementary to (existing alongside them, but improving them) or replace current consent models*. Would, in other words, data donation be something different from (general) consent, but which requires equally an ‘declaration of will’ by the person donating data (just like general consent is a legal instrument that requires the ‘declaration of will’ by the consenting person)? Or would data donation be a specific utilization of consent in a given context (e.g. post-mortem provision of data)? *Solving these issues is not easy, as confirmed also by the fact that the EU is still trying to answer them with respect to data altruism, although the latter has already been implemented as a legal concept* (see above in Chapter 3.2). Furthermore, the answer to these questions would also depend a lot on the kind of implementation that is chosen for Switzerland (data donation as a symbolic concept vs as a legal concept) and the exact scope (i.e. only for post-mortem data donation, or also for data donation for reuse of data from living individuals). At the end of the previous Chapter, some of the pros and cons also in relation to the interaction of data donation with other concepts is explored. *Based on this analysis, the most promising implementation seems to be that of data donation as a legal concept. Whether to make a distinction between in-vivo and posthumous is open for debate. On the one hand, providing explicit rules for posthumous data use has the advantage of filling in a regulatory gap. On the other hand, regulating in-vivo and posthumous data reuse together has the advantage of creating data governance solutions that apply generally, regardless of whether the data subject is still alive or not.* If the latter solution is selected, implementing data donation would require: 1) to create governance structures with the competence of determining which data reuses for research are in the public interests and can then be approved with a simplified regulatory procedure; 2) create a data infrastructure that would still allow people to restrict the reuse of their data, if they wish to (e.g. in the form of opt-out choices).

In any case, *it is important to keep in mind these questions to ensure good communication with the broader public on the ways they can contribute with their data to biomedical research. This also concerns the design of a consent management concept*, which should keep in mind potential confusion from the public on what constitutes a data donation, as well as influence their general attitudes towards the provision of data. *This is one of the tasks that a National Data Coordination Centre could perform*. The creation of this centre was suggested in previous reports.[2,122] The idea is that it will take up the role of trusted mediator between the different health data sources (also offering a catalogue thereof) and the researchers who want to access their data for secondary uses. *If data donation is implemented as a legal concept for data reuse, the centre could help data sources with the implementation of opt-out registers for people who want their data NOT to be used before and/or after their death* (see also the example of the English National Data Opt Out). *It could* *also provide guidelines to define what secondary research in the public interest means.* Such projects could then be authorized to reuse data from living and/or deceased individuals. *For the definition of public interest, a broad one is recommended, including potentially also private researchers – within specifically defined boundaries. At the same time, it would have to exclude those secondary uses of data that generate most distrust in the population* (see also next Chapter).

What do we (not) know about people's attitudes towards the provision of data for research?

The *implementation of data donation and/or the reform of any of the existing channels available for the public to provide their data for reuse should certainly consider what we know – and do not know – about people's attitudes towards the idea of making health and health related data available for research*. As the review of studies on this matter we presented in Chapter 4.3 shows, there is indeed some evidence available, but also many gaps. For a start, we are not aware of any study that focuses specifically on the attitudes of the Swiss population towards posthumous data donation. This is a considerable knowledge gap, since:

1) one potential implementation of data donation concerns indeed the post-mortem case, which is currently a rather a grey area in the Swiss data governance regulatory landscape;
2) the use of data post-mortem involves a different set of risks (e.g. there are much lower risks in terms of violation of informational self-determination for deceased people) and thus likely different attitudes from the public.

Furthermore, the available studies have all slightly different designs, some focusing on the donation of data for specific purposes (e.g. personalized medicine), others differentiating between types of donated data (e.g. personal vs anonymized). *It is thus difficult to draw unequivocal conclusions from the existing evidence*. One useful finding concerns the fact that studies suggest there is a poor understanding of certain essential terminological details. For example, available evidence suggest that people prefer to donate anonymized data, but also that they want to retain certain rights towards it (e.g. of withdrawing the donation or being re-contacted). This is a contradiction, since once data is truly anonymized, it is not possible to recontact participants or to allow them specific rights, since the data is simply not personal anymore. *It would thus be important to provide more information to the public on the differences between anonymized, pseudonymized/coded and uncoded data, before their attitudes towards data donation are measured*. The distinction between these different categories is quite difficult to communicate, especially if a risk-based de-identification approach is used. Studies conducted with researchers who use data in their daily work have shown they also still have many doubts about the boundaries of the categories.[123,124]

Two additional aspects are essential to keep in mind when considering public attitudes toward the provision of data for reuse and their meaningfulness for policymaking. *On the one hand, the fact that public attitude may change a lot depending on cultural elements.* A recent multi-national study on the attitudes of different European peoples towards the provision of data for research has shown substantial differences in preferences between cultural areas (northern Europe vs central Europe vs southern Europe).[125] Being Switzerland at the crossroad of these cultural areas, it would be important to analyze whether different attitudes are present, for example, between different language regions. *On the other hand, it is always* *important to keep in mind that studies on the attitudes towards the provision of data can only go so far*. As one of the studies we presented above explicitly said, research can only explore the *potential* willingness to donate data, but "actual participation rates in human and biobank research consistently remain lower than self-reported, hypothetical willingness."[110] For this reason, the percentages of willingness to donate data always need to be analyzed in the broader context, before creating a potentially misleading narrative of a 'willing' (to provide data) population, whereas actual willingness may be more conditional.[126]

In terms of public attitudes towards the sharing of data for secondary research, below in Table 7 we summarize some of the most important issues to be solved in future empirical research. The National Data Coordination Centre, if created, could help to monitor public acceptance and general attitudes towards the secondary use of data.

Table 7. Recommendations for future research on population attitudes towards data sharing

Recommendation for future empirical research on population attitudes towards data sharing
• Investigate people's data literacy: what is their knowledge (and knowledge gaps) around data processes and terminology (e.g. pseudonymization vs anonymization). • Create surveys with concrete examples/vignettes of secondary data usages rather than generic questions. → E.g. presenting an example of a secondary use research project and asking whether individuals would accept that it goes on without specific consent. • Propose experimental designs that are aimed to reduce social-desirability bias. → E.g. if a survey asks directly "would you donate data for research projects in the public interest", there is a chance that people respond positively, only because they think it is socially desirable. If a survey proposes one hypothetical scenario of secondary research which serves public interest (but without directly mentioning the term), participants may reply with undue less influence. • Study more precisely what type of research people would be happy to donate data for, even with reduced individual control mechanisms (e.g. opt-out rather than opt-in). • Gather evidence on people's preference for the post-mortem secondary use of health data: do they have the same (level of) privacy concerns? Would they accept more research-friendly re-use conditions for data after death?

6. Conclusions

This report had the main objective to provide more clarity on the concept of data donation, its implementation and the relevance for the Swiss data governance context. To do so, we first clarified where the concept of data donation originated. We showed how it derived from the academic context and that it was based on the commonsensical intuition that there needs to be a way to exploit the data of deceased individuals for secondary research, just like it is possible to provide organs post-mortem for the benefit of patients and the healthcare sector. Starting from this, the scientific reflection on the boundaries of this concept began and – although some features were defined, such as the fact that data donation should only be associated to data reused for purposes serving the public good – many basic elements of these concepts remain riddled with uncertainties. We then showed that the blurry lines of the concept of data donation border with other relevant concepts in the field of health data governance, both traditional ones (such as consent) and novel ones (such as data solidarity).

Against this conceptual background, we then reviewed how data donation and related concepts have been implemented in different international contexts. In this review, we started by elucidating the key distinction between a symbolic implementation and a legal implementation. We then explored contexts such as the EU – which through its data altruism model is trying to pursue a legal implementation – or Denmark – whose system of governance of data reuse reminds of a symbolic implementation of data solidarity.

Afterwards, we moved to the Swiss context and showed that there are already some pioneering initiatives that have made explicit reference to the concept of data donation. These used data donation as a frame for data collection activities that were aimed at promoting data reuse for the public good. We then situated these initiatives in the broader context of Swiss health data governance, where recently many changes have been initiated to reinforce the public interest in a freer flow of data. In Chapter 4.3 on the readiness of the Swiss population for data donation, we reviewed studies on the attitudes of the public towards the provision of data for research, an issue on which any implementation of data donation or related concepts is eventually dependent.

Our final reflections moved towards indicating some recommended steps for the way forward concerning data donation in Switzerland. Across the many uncertainties that concern the conceptual boundaries of data donation and the absence of one single clear functioning model for its implementation, the recommendations pinpoint specific lines along which the implementation of data donation in Switzerland could proceed. In so doing, our recommendations are also relevant for the broader debate on how to reform health data governance, given that elements such as the communication with the broader public and their attitudes towards data use are bound to be relevant in any case – be it for the implementation of data donation or the development of a suitable consent management model.

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8. Appendix 1 – Glossary

The following glossary contains a categorization and succinct definition of the most relevant terminologies used in the report. The definition is derived from the literature, and sources are indicated directly or a reference is made to the paragraph of the report where sources are indicated, and a more nuanced definition is made. Translations of the terms are made for informative purposes.

Term	**Definition**	**Translations in** **1) German** **2) French** **3) Italian**
(implementation as a) legal concept	The creation of specific legal rules to implement a concept in the legal framework. For example, data altruism was implemented as a legal concept in the EU (see chapter 3.2), since the term was directly embedded into law (the Data Governance Act) with a specific definition and specific requirements.	1) rechtliches Konzept 2) concept légal 3) concetto legale
(implementation as a) symbolic concept	The use of a concept only as a 'frame', in order to convey a certain message related to a policy or project. For example, the Universal Declaration on the Human Genome and Human Rights, says that "The human genome […] is the heritage of humanity". This is meant symbolically to indicate that human genome has to be looked at as something that should be protected and unites all humanity. It does not mean literally that the genome is a "common heritage" belonging to all humanity as a tangible good. Similarly, a symbolic implementation of data donation does *not* imply that data are literally 'donated' (in the sense of property transfer, also due to the fact that data are not subject to property rights). Speaking of data donation in a symbolic sense simply serves the purpose of framing data transfers as acts of altruism made for non-profit causes, to encourage individuals to share data. See also Chapter 3.1.	1) symbolisches Konzept 2) concept symbolique 3) concetto simbolico
Blanket consent	Consent for reusing data for any purposes, without specific limitations. See here. In Switzerland, this is rather	1) Generalkonsent 2) consentement général 3) Consenso generale

	equivalent to the General consent, hence the translation for this report is the same.	
Broad consent	Consent for reusing data for a broad set of secondary research purposes, but with some limitations (e.g. only research projects approved by an Ethics Committee). See here.	1) breite Einwilligung 2) consentement large 3) consenso ampio
Commercial interest	As opposed to "Public interest", it refers to the idea that reusing data can also serve mainly the financial profit of private institutions. It is therefore debated whether the secondary use of data for such interest should be facilitated. For a summary of the arguments in relation to commercial interests and profit in relation to health data reuse, see here. For an overview of how distinguishing between secondary use of research for the public vs commercial interest is difficult, see here.	1) kommerzielles Interesse 2) intérêt commercial 3) interesse commerciale
Common good	This concept is used as a quasi-synonym to "Public interest" in this report.	1) Gemeinwohl 2) bien commun 3) bene comune
Data altruism	This concept was codified by the EU in the Data Governance Act to identify "the voluntary sharing of data on the basis of the consent of data subjects to process personal data pertaining to them[…] where they make their data available for objectives of general interest" (see here). In this context, general interest is used as a quasi-synonym to public interest (see glossary item below).	1) Datenaltruismus 2) Altruisme en matière de données 3) altruismo dei dati
Data donation	As evident in the report, there is no shared definition. In general, it refers to the possibility of donating (in the sense of providing) data for secondary uses (especially research) that serve a public interest, common good, or another socially-desirable purpose. See the Chapter 2 for more details.	1) Datenspende 2) don de données 3) donazione di dati
Data governance	This refers to the sum of "rules and policies on the exchange [and re-use] of data; people and organizational body which make and operationalize the rules; and concrete processes that	1) Data Governance 2) gouvernance des données 3) governance dei dati

	people follow to process the data". See here.	
Data philanthropy	The term refers to the donation of data from private companies for purposes that benefit society at large. See here.	1) Datenphilanthropie 2) philanthropie de données 3) filantropia dei dati
Data solidarity	This is a recently proposed model for the governance of secondary use of data. Rather than placing emphasis on individuals and their powers to steer what data is used for, it proposes collective governance that facilitates data uses for the common good and reduces (or even prohibits) secondary uses that are high-risk and only serve private interests. See here.	1) Datensolidarität 2) solidarité de données 3) solidarietà dei dati
Dynamic consent	This is a model of consent which is based on the idea of personalizing consent for the reuse of data, and engaging individuals (e.g. by altering their consent choices over time). For a theoretical overview, see here. For a concrete example of an initiative implementing it, see here.	1) dynamische Einwilligung 2) consentement dynamique 3) consenso dinamico
General consent	In the international literature, this is sometimes used as a synonym of broad consent, see here. However, in the specific context of Switzerland, this is the name of a specifically recognized type of consent, whereby individuals generally agree to the reuse of data for research, thus more similar to blanket consent. See also here.	1) Generalkonsent 2) consentement général 3) consenso generale
In-vivo data donation	It refers to conceiving or implementing data donation as an instrument for living individuals to donate their data for secondary uses related to research in the public interest. See the difference with posthumous data donation. See also here.	1) in-vivo Datenspende 2) don des données in vivo 3) donazione di dati
Meta consent	This is a model of consent based on the idea that people should be allowed to decide themselves which type of consent they want to adopt for allowing the reuse of data for research. See here.	1) Meta-Einwilligung 2) méta consentement 3) meta-consenso
Posthumous data donation	It refers to conceiving or implementing data donation as an instrument for allowing individuals to donate their data	1) posthume Datenspende 2) dons de données après la mort

	so that it can be reused for research after their death. See the difference with in-vivo data donation. See also here.	3) donazione di dati da persone viventi
Public interest (or common good or general interest)	In this report, it refers to the idea that data donation should not be used to permit/legitimize any type of secondary uses, but only the secondary uses for research that serves the good of the community, of the public (and not private profit). It can also be defined as general interest or common good (quasi-synonyms in this context). However, a clear and uniform definition of what constitutes public interest in this context is very debated. Some argue also reuses by for-profit companies (e.g. pharma) can serve the public interest. Others have shown that this can create controversies.	1) öffentliches Interesse 2) intérêt public 3) interesse pubblico Or 1) Gemeinwohl 2) bien commun 3) bene comune Or 1) allgemeines Interesse 2) intérêt général 3) interesse generale
Reuse of data	In this report, it is used a synonym of secondary use of data.	1) Weiterwendung von Daten 2) réutilisation des données 3) riutilizzo dei dati
Secondary use of data	The use of data for a purpose different from the one they were collected. For example, the use of routinely collected data from the clinic that are then used a second time for public health research. See here.	1) Sekundärnutzung 2) utilisation secondaire des données 3) uso secondario dei dati
Specific consent	This is the traditional model of consent for any type of research, also if data-based. It entails the requirement to ask for consent to individuals whose data are used for each single research project. See here.	1) spezifische informierte Einwilligung 2) consentement éclairé spécifique 3) consenso informato specifico
Value-based consent	This is a newly proposed model of consent which is based in collecting individuals value preferences, and regulate their secondary use of data for research based on that. See here.	1) wertbasierte Einwilligung 2) consentement basé sur les valeurs 3) consenso valoriale