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# Biobanks, personalised medicine, and artificial intelligence: legal and ethical perspectives

*Karl-Philippe Bretel*

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ΠΡΩΤΟΤΥΠΗ ΕΡΓΑΣΙΑ

# Βιοτράπεζες, εξατομικευμένη ιατρική και τεχνητή νοημοσύνη: νομικές και ηθικές προοπτικές

**Karl-Philippe Bretel**
*LLM., Πανεπιστήμιο Παρισιού VIII (Vincennes)*

karl.bretel@gmail.com

## ΠΕΡΙΛΗΨΗ

Οι βιοτράπεζες και η εξατομικευμένη ιατρική έχουν καταστεί κεντρικοί πυλώνες της σύγχρονης βιοϊατρικής έρευνας, αντανακλώντας μια ευρύτερη φιλοδοξία για μετάβαση σε πιο ακριβή, προληπτικά και επικεντρωμένα στον ασθενή μοντέλα υγειονομικής περίθαλψης. Καθιστώντας δυνατή τη συλλογή σε μεγάλη κλίμακα και τη μακροπρόθεσμη αποθήκευση βιολογικών δειγμάτων και συναφών δεδομένων, οι βιοτράπεζες παρέχουν τη βασική υποδομή που απαιτείται για την πρόοδο στη γονιδιωματική, τις θεραπείες ακριβείας και την ιατρική καινοτομία. Η ενσωμάτωση της τεχνητής νοημοσύνης (AI) σε αυτό το οικοσύστημα ενισχύει περαιτέρω το δυναμικό τους, ενώ ταυτόχρονα δημιουργεί σύνθετα νομικά και ηθικά ζητήματα.

Το παρόν άρθρο εξετάζει τον εξελισσόμενο ρόλο των βιοτραπεζών στην εξατομικευμένη ιατρική από νομική και ηθική άποψη, με ιδιαίτερη έμφαση στον κανονιστικό κατακερματισμό που χαρακτηρίζει αυτόν τον τομέα σε διεθνές επίπεδο. Παρά την ύπαρξη προτύπων διαπίστευσης που έχουν αναπτυχθεί από διεθνείς οργανισμούς, οι βιοτράπεζες εξακολουθούν να διέπονται κυρίως από εθνικά νομικά πλαίσια. Αυτή η έλλειψη εναρμόνισης έχει ως αποτέλεσμα σημαντικές διαφορές όσον αφορά τα μοντέλα συγκατάθεσης, τα μέτρα προστασίας των προσωπικών δεδομένων, την ανταλλαγή δεδομένων σε διεθνές επίπεδο και τη συμμετοχή ιδιωτικών φορέων. Μέσω μιας συγκριτικής ανάλυσης επιλεγμένων χωρών, το άρθρο υπογραμμίζει τον τρόπο με τον οποίο οι διαφορετικές ρυθμιστικές προσεγγίσεις διαμορφώνουν τόσο τις ερευνητικές πρακτικές όσο και την προστασία των ατομικών δικαιωμάτων.

Εκείνο που υποστηρίζεται, τελικά, είναι ότι η βιώσιμη ανάπτυξη των βιοτραπεζών και της εξατομικευμένης ιατρικής που βασίζεται στην τεχνητή νοημοσύνη εξαρτάται από ισχυρούς μηχανισμούς διακυβέρνησης, διαφανείς πρακτικές συγκατάθεσης και ισχυρή ηθική εποπτεία. Οι επιτροπές δεοντολογίας, οι νομικές εγγυήσεις και η διεθνής συνεργασία συνιστούν αναγκαίους όρους για να διασφαλιστεί ότι η καινοτομία σε αυτόν τον τομέα ωφελεί το σύνολο της κοινωνίας χωρίς να υπονομεύει τα ατομικά δικαιώματα ή την κοινωνική ισότητα.

**Λέξεις-κλειδιά:**
βιοτράπεζες, εξατομικευμένη ιατρική, τεχνητή νοημοσύνη, διακυβέρνηση δεδομένων υγείας, συγκατάθεση, νομοθεσία για την προστασία των δεδομένων

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DEMOKRITOS

ORIGINAL ARTICLE

# Biobanks, personalised medicine, and artificial intelligence: legal and ethical perspectives

**Karl-Philippe Bretel**
*LLM., University of Paris VIII (Vincennes)*

karl.bretel@gmail.com

## ABSTRACT

Biobanks and personalised medicine have become central pillars of contemporary biomedical research, reflecting a broader ambition to move towards more precise, preventive, and patient-centred healthcare models. By enabling the large-scale collection and long-term storage of biological samples and associated data, biobanks provide the foundational infrastructure required for advances in genomics, precision therapies, and data-driven medical innovation. The integration of artificial intelligence (AI) into this ecosystem further amplifies their potential, while simultaneously raising complex legal and ethical challenges.

This article examines the evolving role of biobanks in personalised medicine through a legal and ethical lens, with particular attention to the regulatory fragmentation that characterises this field at the international level. Despite the existence of accreditation standards and ethical declarations developed by international organisations, biobanks remain primarily governed by national legal frameworks. This lack of harmonisation results in significant differences between jurisdictions regarding consent models, data protection safeguards, international data sharing, and the involvement of private actors. Through a comparative analysis of selected countries, including France, Sweden, and the United States, the article highlights how divergent regulatory approaches shape both research practices and the protection of individual rights.

Ultimately, this study argues that the sustainable development of biobanks and AI enabled personalised medicine depends on robust governance mechanisms, transparent consent practices, and strong ethical oversight. Ethics committees, legal safeguards, and international cooperation remain essential to ensuring that innovation in this field benefits society as a whole without undermining individual rights or social equity.

**Keywords:**
biobanks, personalised medicine, artificial intelligence, health data governance, consent, data protection law

Biobanks and precision medicine reflect this ambition to create patient-centred medicine. There is not only a desire to change the way we perceive medicine, but also an ambition to better understand the human body.

The Organisation for Economic Co-operation and Development (OECD) has since 2001 defined biobanks as structures that professionalise the management of biological resources for research purposes. Otherwise, for the OECD Biological Resource Centres ( BRCs), are "centres for the conservation of living cells, the genome of various organisms, and information on the heredity and functions of biological systems. BRCs must meet the high standards of quality and expertise demanded by the international research community and industry for the dissemination of information and biological materials".[1]

According to the OECD, the aim of these biobanks is to support the transformation of basic research findings into health products, for the benefit of the health sector and the economy at national and international level[2].

Today, there are almost 374 accredited biobanks registered worldwide.[3] For example, Sunnybrook Health Sciences Centre is an academic health sciences centre affiliated with the University of Toronto. Where the biobank will facilitate leading-edge research by Sunnybrook Research Institute (SRI) researchers and their collaborators to understand the biology of disease, develop new treatments and advance personalised medicine.[4] The world's largest biobank is in the non-profit research centre of the Medical University of Graz in Austria. Around 20 million individual specimens of body fluids and human tissue are stored there. [5]

So, the question is: how can biobanks and personalised medicine using artificial intelligence have a positive impact on the medicine of the future?

For now, there are currently no uniform regulations governing biobanks (I). In addition, there are ethical issues surrounding the future of human beings. Finally, artificial intelligence is likely to revolutionise the impact of personalised medicine and biobanks (II).

## I. A fragmented regulatory framework

There are international accreditations for biobanks (A), but most regulations are at national level (B).

### *A. International legislation*

Strictly speaking, there is no international standard regulating the world of biobanks.[6] However, accreditation of biobanks has been developed to give patients trust should they wish to donate their sample to these research institutes. Indeed, there is the IS0 20387 [7]standard developed by The International Organisation for Standardisation. This organisation was founded in 1947 to create international standards in the industrial and commercial fields and has 171 member countries.

Article 1 of ISO 20387 states that: "This document specifies general requirements for the competence, impartiality and consistent operation of biobanks including quality control requirements to ensure biological material and data collections of appropriate quality.

This document is applicable to all organisations performing biobanking, including biobanking of biological material from multicellular organisms (e.g.

1 *Arrighi N, Liney T, Mitov A, Onivogui GL.Les biobanques, des structures essentielles à la recherche médicale. Med Sci (Paris) 2020, 36:274-276:*

2 *Fiant O. Biobanques médicales et génomique fonctionnelle en France. Open Edition Journals, 30.6.2019.*

3 *University of British Columbia Office of Biobank Education Research, Canadian Tissue Repository Network. BIOBANK RESSOURCE CENTER biobanking.org, 2024.*

4 *Ibidem.*

5 *Biobanking.org.10 Largest Biobanks in the World. Biobanking.org ,17.9.2021.*

6 *Sprumont D, Talanova V. La réglementation des biobanques et des banques de données de santé en Europe: Étude de droit comparé. Online Federal Public Health Platform (OFSP), 14.6.2018,8.*

7 *ISO.ISO 20387:2018 Biotechnology — Biobanking — General requirements for biobanking. Online Browsing Platform (OBP), 2018.*

human, animal, fungus and plant) and microorganisms for research and development.

Biobank users, regulatory authorities, organisations and schemes using peer-assessment, accreditation bodies, and others can also use this document in confirming or recognising the competence of biobanks."[8]

However, this is not the only ISO standard on biobanks, but it is the most advanced. There is also ISO GUIDE 34[9].

On an international level, the World Medical Association (WMA) was founded on 18 September 1947 with the aim of reaching a consensus on medical ethics and plays a major role in scientific research. It has nearly 118[10] national associations, and approximately 1,900 individual members who are physicians in 2023.[11] This association has promulgated the Declaration of Helsinki in 1964 and Taipei in 2016. These declarations set out several ethical principles applicable to medical research involving human beings.

For example, at point 19 the Declaration of Taipei encourages the creation of ethics committees for biobanks. "An independent ethics committee must approve the establishment of Health Databases and Biobanks used for research and other purposes. In addition, the ethics committee must approve use of data and biological material and check whether the consent given at the time of collection is sufficient for the planned use or if other measures must be taken to protect the donor."[12]

However, these declarations are not legally binding; they encourage their members to adopt this vision of medical research, but they are not, strictly speaking, international laws.

Furthermore, The Council for International Organisations of Medical Sciences (CIOMS), an organisation founded in 1949 and made up of 40 international, national and associate member groups representing the biomedical sciences community[13], in collaboration with the World Health Organisation (WHO), published in 2016 "The International Ethical Guidelines for Health-related Research Involving humans". [14] It is composed of 25 guidelines and point 11 underlines the conditions for collecting, storing and using biological samples and their data: "When biological materials and related data, such as health or employment records, are collected and stored, institutions must have a governance system to obtain authorisation for future use of these materials in research. Researchers must not adversely affect the rights and welfare of individuals from whom the materials were collected. When specimens are collected for research purposes, either specific informed consent for a particular use or broad informed consent for unspecified future use must be obtained from the person from whom the material originally is obtained."

Because there are no international standards, only recommendations or guidelines in the field of biobanks, I decided to compare different countries and their legislation on this subject during my study.

8 *Ibidem.*

9 *Dagher G. Biobanking and bioresources ISO TC 276/WG2. INSERM, 7.2017,17.*

10 *World Medical Association. Members: Who Can Be a WMA Member? World Medical Association, 2026.*

11 *World Medical Association. Statement on registration fees of WMA meetings. World Medical Association, 2026.*

12 *World Medical Association.WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks.World Medical Association, 10.2016.*

13 *Haunschild R, Kays J, Rõgo L, Kays M. Bibliometric analysis of publications that cited the CIOMS 2016 "International ethical guidelines for health-related research involving humans". Heliyon 2024, 10(17): e36833, 15.9.2024.*

14 *Council for International Organisations of Medical Sciences, World Health Organisation. International Ethical Guidelines for Health-related Research Involving Humans. CIOMS, 2016.*

### *B. Specificities between States*

The list of countries chosen are Sweden, Norway, Estonia, Germany, France, United Kingdom, Netherlands, Greece, Latvia, Lithuania, Australia, Canada, India, USA, Taiwan, China and Switzerland.

The aim was to get a cross-sectional view of most of the world's scientific centres in terms of their legislation on biobanks, data protection, consent and whether data can be reused by companies. This comparative study takes the form of several tables to give a better idea of the different ways in which different countries operate.

In this study, I will only show the part for France, Sweden and the United States because of the limitation requested.

| Country | Specific legislation | Consent | Data protection | International Sharing | Access Limitation |
|---|---|---|---|---|---|
| France | NO [1] | HIGH [2] | GDPR, loi française «Informatique et Libertés » de 1978[3] | YES ISBER [4] BBMRI-ERIC observer [5] | High[6] |
| USA | NO [7] | Moderate [8] | HIPAA specificity between States, U.S. Privacy Act of 1974, COPPA, and the Gramm-Leach-Bliley Act[9] | YES ISBER [10] | Moderate [11] |

1 *Arrighi N, Messaoudi Z, Soltani N, Arrighi N. Bioéthique : l'existence des contraintes légales et réglementaires des biobanques. Med Sci (Paris), 3.2020,280.*
2 *Cohorte Constance.BIOBANQUE. Cohorte Constance, 2024.*
3 *Bercy Infos.Le règlement général sur la protection des données (RGPD), mode d'emploi. economie. gouv, 11.4.2023.*
4 *ISBER.ISBER – Annual Report 2023. ISBER, 2023,9.*
5 *BBMRI-ERIC. Member States National Nodes Contact for Local Biobanks. BBMRI-ERIC, 2024.*
6 *Biobanking.org.10 Largest Biobanks in the World. Biobanking.org ,17.9.2021.*
7 *Harrell HL, Rothstein MA. Biobanking Research and Privacy Laws in the United States. J Law Med Ethics, 3.2016.*
8 *Ibidem.*
9 *Bloomberg Law. Consumer Data Privacy Laws. Bloomberg Law, 2024.*
10 *ISBER.ISBER – Annual Report 2023. ISBER, 2023,9.*
11 *Cadigan RJ, Conlon I, Davis AM, Edwards TP, Evans JP, Henderson GE, Nelson AG, Weiner BJ, Zimmer C. Characterising biobank organisations in the U.S.: results from a national survey. Genet Med, 1.2013.*

| | | | | | |
|---|---|---|---|---|---|
| Sweden | YES [12] | High[13] | RGPD, Data Protection Act (2018:218) (the "Data Protection Act") and the Data Protection Ordinance (2018:219) [14] | YES BBMRI-ERIC, ISBER et ESBB[15] | High[16] |

| Country Legal | Private Sector | Public Research | Hospital Samples | Legal Text | WMA Member<br>Signed Declaration of Helsinki<br>Signed Declaration of Taipei |
|---|---|---|---|---|---|
| France | YES [17] | YES [18] | YES [19] | Article L1211-1 à L 1211-9 Code de la santé publique[20], Loi de Bioéthique,[21] RGPD, loi française « Informatique et Libertés » de 1978[22] | YES [23] |

12 *Ministry of Health and Social Affairs of Sweden. A New Biobank Act. Biobank SVERIGE, 16.2.2023.*
13 *Biobank Sweden. Document, change of consent. Biobank Sweden, 2024.*
14 *DLA Piper. Law in Sweden.DLA Piper – Data Protection Laws of the World, 22.1.2024.*
15 *Biobank Sweden. About Biobank Sweden. Biobank Sweden, 26.2.2024.*
16 *OneTrust. Sweden. OneTrust Data Guidance 2024.*
17 *Musso M. Former les « biobankers » de demain. Université Côte d'Azur, 2024.*
18 *Ibidem.*
19 *Ibidem.*
20 *InfoCancer. Biobanques. InfoCancer, 2024.*
21 *Arrighi N, Messaoudi Z, Soltani N. Bioéthique : l'existence des contraintes légales et réglementaires des biobanks / Legal and ethical considerations for the use of biobanks. Med Sci (Paris), 2020, 36.*
22 *Bercy Infos.Le règlement général sur la protection des données (RGPD), mode d'emploi. economie.gouv, 11.4.2023.*
23 *World Medical Association. Members: Who Can Be a WMA Member? World Medical Association, 2026.*

| | | | | | |
|---|---|---|---|---|---|
| USA | YES [24] | YES [25] | YES [26] | Health Insurance Portability and Accountability Act (HIPAA) (1996, ongoing revisions) HIPAA specificities between U.S. States Privacy Act of 1974, COPPA, and the Gramm-Leach-Bliley Act,[27]<br>Common Rule (45 CFR 46) (Revised 2018)[28] | YES [29] |
| | | | | | |
| Sweden | YES [30] | YES [31] | YES[32] | Biobanks act 2003, révisée 2023[33], GDPR 2018, Data Protection Act (2018:218) (the "Data Protection Act") et the Data Protection [34]Ordinance (2018:219) | YES[35] |

The first table shows that neither France nor the United States has a specific law for biobanks, unlike some countries such as Sweden.

24 *Merck. Biorepository & Storage. Merck, 2024*
25 *Lyle L. Revived USA Health Biobank offers comprehensive services for researchers. University of South Alabama, 19.1.2021.*
26 *Ibidem.*
27 *Bloomberg Law. Consumer Data Privacy Laws. Bloomberg Law, 2024.*
28 *U.S. Government.45 CFR 46. Office for Human Research Protections, 2018.*
29 *World Medical Association. Members: Who Can Be a WMA Member? World Medical Association, 2026.*
30 *Reichel J, Slokengerga S, Tzortzatou O. Sweden, GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe. Springer, 1.2021,380-386.*
31 *Ibid,406.*
32 *Ibid,380.*
33 *Biobank Sweden. About Biobank Sweden. Biobank Sweden, 26.2.2024.*
34 *DLA Piper. Law in Sweden.DLA Piper – Data Protection Laws of the World, 22.1.2024*
35 *World Medical Association. Members: Who Can Be a WMA Member? World Medical Association, 2026.*

In terms of data protection and consent, France and Sweden have a much more protective law because of the GDPR , whereas the United States can circumvent consent thanks to the Health Insurance Portability and Accountability Act (HIPAA), which was published on 21 August 1996. Article 45 CFR § 164.506[15] states that health information protected by HIPAA can be disclosed for processing purposes without the individual's consent. [16]

In terms of international sharing, France Sweden and the United States of America, through their various biobanks, are members of the International Society for Biological and Environmental Repositories (ISBER), founded in 1999 with the aim of promoting best practice in the management of biological and environmental samples, while encouraging collaboration and the sharing of information between its members (1059 members in 2023).[17] Sweden is also Member of the BBMRI-ERIC.

The second table shows that results are shared between the private, public and hospital sectors in all the countries in order to promote research. In addition, it lists most of the laws that are fundamental to biobank research, such as article L 1211-1 of the French Public Health Code, which governs the transfer and use of human samples for medical research purposes.

Finally, all the countries are signatories of the Declarations of Helsinki and Taipei. In the field of personalised medicine and the use of biobanks, several ethical issues are emerging, particularly around consent and the potential economic benefits for certain companies.

15 *Ministry of Health and Social Services. 45 FR § 164.506 – Uses and disclosures to carry out treatment, payment, or health care operations. Cornell Law School Legal Information Institute, 1.25.*

16 *Iubenda. GDPR vs HIPAA – What Are the Differences and How to Comply? Iubenda, 2024.*

17 *ISBER.ISBER – Annual Report 2023. ISBER, 2023,7.*

## II. Ethics between aspiration and progress in the field of biobanks and personalised medicine

This section looks at ethics and consent (A), plans and laws for personalised medicine and artificial intelligence (B), and the economic potential of these new technologies (C).

### *A. Ethics and consent in future medicine*

First, precision or personalised medicine can be defined as: "A medical model that aims to provide tailor-made prevention and treatment strategies for defined groups of individuals. While there is no universally accepted definition, the EU Health Ministers in their Council conclusions on personalised medicine for patients, published in December 2015, defined personalised medicine as: A medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention."[18]

In addition, the broader concept of '4P' medicine (Predictive, Personalised, Preventive and Participatory), defined in 2013 by the American biologist Leroy Hood, is in line with this research.[19]

Finally, artificial intelligence, which is an integral part of this transformation, is defined by IBM as: A technology that enables computers and machines to simulate human learning, comprehension, problem solving, decision making, creativity and autonomy. Alone or combined with other technologies (e.g. sensors, geolocation, robotics), AI can perform tasks that would otherwise require human intelligence or intervention. Digital assistants, GPS guidance, autonomous vehicles and generative AI tools (such as Chat GPT from Open AI)

18 *Directorate-General for Health and Food Safety. Personalised medicine. European Commission, 2024.*

19 *Delmont-Koropoulis A. Proposition de loi relative à l'innovation en santé. Sénat, 16.2.2022.*

are just a few examples of AI in the news and in our daily lives. As a field of computer science, artificial intelligence encompasses (and is often mentioned alongside) machine learning and deep learning. These disciplines involve the development of AI algorithms, modelled on the decision-making processes of the human brain, that are capable of 'learning'.[20]

In the field of data protection, I have taken the GDPR as an example because of its importance worldwide. Many countries have drawn inspiration from the RGPD to develop their own data protection regulations, for example India, which adopted The Digital Personal Data Protection ( DPDP ) Act in 2023. Therefore, Article 89 of the GDPR permits the processing of personal data for specific research purposes, and allows derogations from individual rights, while imposing appropriate safeguards to protect the rights and freedoms of the individuals concerned. In addition, this article encourages anonymisation and pseudonymisation to ensure that personal data cannot be attributed to an identifiable natural person. This article demonstrates that the notion of public interest allows for derogations in personal data protection. This notion of public interest, which allows individual rights to be transgressed, is mentioned nearly 70 times in the GDPR, as Santa Slokenbarga points out in his book GDPR and biobanking[21].

Secondly, samples cannot be taken without the informed consent of the individuals. This informed consent can be found in every country in the world when it comes to research (biobanking, artificial intelligence or personalised medicine). According to the Clermont Ferrand University Hospital, it can be defined as follows: "Free consent that does not have to be obtained under duress and renewed for each new medical act. And informed in the sense that the person must have been informed in advance of the procedures he or she is to undergo, of the frequent or serious risks that are normally foreseeable in the light of current scientific knowledge, and of the consequences that these could entail. "[22]Furthermore, article L 1111 - 4 of the French Public Health Code reminds us that informed consent is limited in the case of minors and adults under guardianship, when the treatment is orchestrated by health professionals.

Accordingly, these informed consents lay down several essential principle's participants must be aware that their samples may be re-used in the future for unspecified research purposes. Secondly, that its samples may be shared with other researchers or institutions, and therefore set out the risks involved in transferring data outside the European Union. In addition, the data collected could lead to commercial exploitation. However, participants can ask whether any results have been obtained from their samples and this will be explained to them. They must also know how long the samples will be kept. In addition, the data must be anonymised to ensure confidentiality. Lastly, participants must have been informed of their right to withdraw their consent and the procedure for doing it.[23]

From an ethical point of view, personalised medicine with the help of artificial intelligence must be based on several principles. Individuals may not be discriminated against in the processing of their data on the grounds of their origin or through the processing of their genetic data. As a result, in the European Union, it is not possible for insurance companies to discriminate against people based on their samples if, for example, they turn out to be victims of an irreversible genetic disease. In addition, Article L 1211 - 2 of the French Public Health Code states that: "The removal of elements from the human body and the collection of its products may not be carried out without the donor's prior consent. This consent may be revoked at any time. The use of elements and products of the human body for a medical or scientific purpose other than that for which they were removed or collected is possible, unless the person from whom they

20 *IBM. What Is Artificial Intelligence (AI)?. IBM, 2024.*

21 *Reichel J, Slokengerga S, Tzortzatou O. Sweden, GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation across Europe. Springer, 1.2021,24.*

22 *Centre Hospitalier Universitaire de Clermont-Ferrand. Consentement libre et éclairé. Centre Hospitalier Universitaire de Clermont-Ferrand, 2024.*

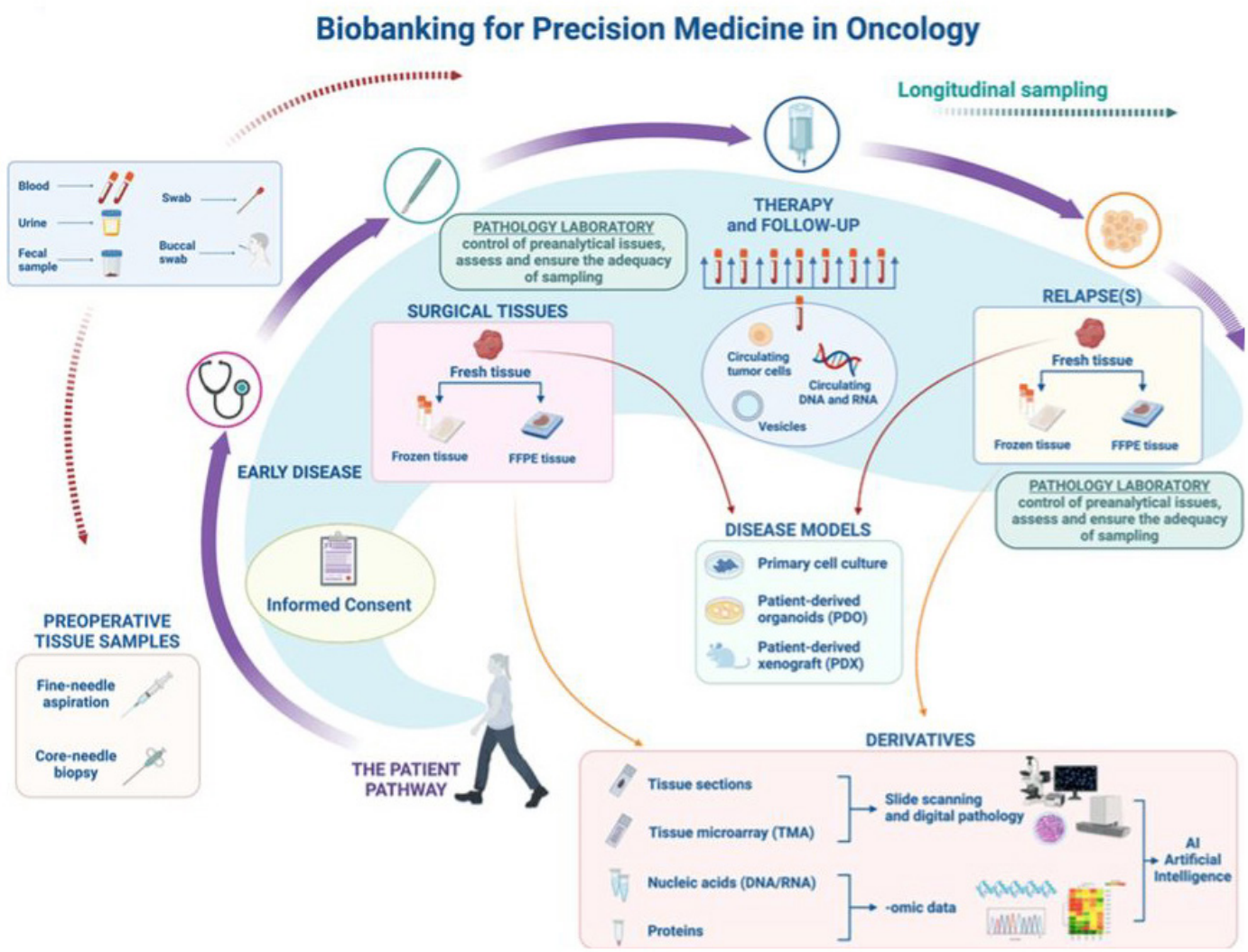
23 *Directorate-General for Communication. When Is Consent Valid? European Commission, 2024.*

were removed or collected expresses an objection, duly informed in advance of this other purpose." Lastly, the samples must not be sold, they must come from donations because of the abuses that this could lead to. The first victims would be the working classes, who would choose to sell their bodies for economic gain rather than to advance science.

In the field of biobanks, precision medicine and the use of artificial intelligence, one of the main safeguards is the creation of ethics committees in different countries.

This diagram describes the pathway needed to achieve high-quality personalised medicine using artificial intelligence and biobanks. First, the patient gives their consent and biological samples such as blood or urine are taken from them. These are then sent to a laboratory (biobank) for processing. Using these samples, laboratories are developing models such as Patient-Derived Organoids (PDOs) to gain a better understanding of personalised medicine. The data acquired is then processed in part by artificial intelligence to analyse the genetic data that will enable the samples to be analysed more efficiently.

Because of the acceleration of artificial intelligence, there are also questions about how governments can legally incorporate precision medicine and artificial intelligence into healthcare.



### *B. Personalised medicine and artificial intelligence - plans and laws*

This section will look at the raising of ambitions in personalised medicine and artificial intelligence, particularly in the European Union, because the legislative framework in Europe is often more protective than that of its partners. The European Commission is supporting personalised medicine through its plan: « Personalised Medicine 2020 and beyond – Preparing Europe for leading the global way (PerMed) ». The main objectives of the CSA PerMed were to:

"• Identify relevant fields, organisations, current national, European and selected international initiatives, policies, and capacities related to Personalised Medicine based on an inventory and synthesis of existing relevant information

- Step up coordination efforts between European key players and stakeholders in the different areas of Personalised Medicine (e.g., governmental and funding bodies, researchers, private sector, regulators and policy makers, payers and insurers, service providers and healthcare professionals, as well as citizens/patients) to create synergies
- Highlight European and national showcases and best practice examples for already successful approaches in all areas related to Personalised Medicine
- Complement existing activities by identifying and promoting promising research topics
- Develop a strategic research and innovation agenda with general recommendations and research activities which could foster the further implementation of Personalised Medicine (PM) in Europe and beyond."[24]

In the European Union, a few laws have been passed in response to personalised medicine.[25] The three main ones are:

- The first, the legislation on in vitro diagnostics and medical devices, aims to adapt EU legislation to technological and scientific progress in this sector and to introduce a better consultation process for diagnostics in vitro. This is Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.
- The second, the most famous in the field of data protection the General Data Protection Regulation (GDPR) (See Article 9§2.H "processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;".
- The third is the regulation on clinical trials, which aims to simplify the conduct of clinical trials and therefore facilitate research into therapies using personalised medicine. This is Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC.

For artificial intelligence in relation to personalised medicine, the Artificial Intelligence Act, ( IA ACT ) adopted on 13 March 2024 provides a legal framework for advances in new technologies in the field of medicine.

Artificial intelligence in the field of health are among the high-risk artificial intelligences, as set out in Annex I. The article 6 of the Artificial Intelligence Act states that : "that AI system shall be considered to be high-risk where both

24 *CORDIS.Final Report Summary – PERMED (Personalised Medicine 2020 and Beyond – Preparing Europe for Leading the Global Way). European Commission, 2024.*

25 *Directorate-General for Health and Food Safety. Personalised medicine. European Commission, 2024.*

of the following conditions are fulfilled: (a) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I; (b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I."[26]

However, the European Union does not want to hinder innovation in the research field, that is why it has authorised, in Article 59 of the AI ACT, the fundamental notion of public interest, which makes it possible to derogate from certain restrictions normally imposed within the common framework for research and innovation.[27]

Today, 98% of healthcare organisations have adopted or are considering an AI strategy. The Food and Drug Administration (FDA) has approved 700 AI-enabled medical devices and plans to accelerate more AI approvals. But 65% of doctors have doubts about these new technologies. Hence, the need for safe, trustworthy AI in healthcare. For personalised medicine to be effective, we also need to make sure that all different ethnic groups participate in the programmes, because although human beings are 99.9% similar, there are disparities between populations.

Finally, these new technologies offer enormous economic potential.

## *C. The commercialisation and cost of biobanks, personalised medicine and artificial intelligence in medicine*

Personalised medicine is a revolution, and the progress made in recent years will enable us to imagine a more malleable and safer medicine for patients. For example, in the early 2000s, when the first attempts were made to sequence DNA, the cost was exponential; today, it costs just a few thousand euros, and research is advancing. These therapies could become the key to fighting cancer. For the time being, however, the results are certainly on the right track in the fight against tumours, but for most individuals, they still only prolong life expectancy by a few months. Meanwhile, the cost of this precision medicine can run from 50,000 to 100,000 for a single cure.[28] For example, Novartis AG's TECARTUS CAR T cell therapy, approved as a personalised medicine, costs between $300,000 and $400,000, while AMVUTTRA (vutrisiran) costs between $85,000 and $115,000.[29]

The total value of biobanks (77 billion in 2023)[30], precision medicine (79 billion in 2024[31]) and artificial intelligence (14 billion in 2024)[32], and 1.2 billion in the field of personalised medicine) [33]would reach almost 200 billion euros worldwide in 2024. This also reflects an increasing disparity between the world's 3 major economic hubs - East Asia, Europe and North America - and the rest of the world.

Furthermore, these new technologies, and in particular artificial intelligence, could reduce the cost of healthcare. In Belgium, for example, Mathieu Michel, Secretary of State for Digital Affairs, believes that the use of AI could lead to savings nearly 12 billion out of the 36 billion budgets for healthcare.[34]

26 *European Commission. Artificial Intelligence Act. European Commission, 13.3.2024,53.*

27 *Idem, p.91.*

28 *Jordan B.Cancer : les trois époques de la médecine personnalisée / Chroniques génomiques – Cancer : trois époques de la médecine personnalisée.Med Sci (Paris) 2017, 33(10).*

29 *Market and Market. Precision Medicine Market. Market and Market, 9.2023.*

30 *Precedence Research. Biobanking Market Size, Share, and Trends 2024 to 2034.Precedence Research, 2023.*

31 *Global Market Insights. Taille du marché de la médecine de précision. Global Market Insights, 4.2024.*

32 *Global Market Insights. Artificial Intelligence in Healthcare Market Size. Global Market Insight, 6.2024.*

33 *Global Market Insights. Artificial Intelligence in Precision Medicine Market Size. Global Market Insights, 6.2023.*

34 *Bruxant M.12 milliards économisés dans le domaine de la santé grâce à l'intelligence artificielle ? Mathieu Michel y croit. RTL Info, 6.2.2024.*

However, the commercialisation and market size of artificial intelligence for biobanking and personalised medicine raises several ethical questions. First, security and confidentiality, especially if data is hacked. The risk of a lack of informed consent: the further technology advances, the more difficult it will be for people to understand what's at stake, particularly with the lack of explicability of artificial intelligence algorithms, the problem of black boxes and algorithmic bias. The question of liability in the event of algorithmic errors between developers, users or medical research centres (laboratories, hospitals, etc.). Finally, there is the risk of developing a two-tier medical system, with an affluent class able to pay for care, and the middle and working classes excluded from these discoveries.

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