

# Current aspects in biobanking for personalized oncology investigations and treatments



ONCOLOGY

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## Abstract

**Background/Aim.** A biobank is an organization that gathers, refines, preserves and provides access to biospecimens along with relevant clinical data that can be used in applied or clinical research. Biobanking is a critical component of the scientific foundation for personalized medicine; this implies the accessibility of high-quality human biospecimens, such as blood, tissue, and other body fluids, along with the patient clinical data that goes with them.

**Methods.** This paper summarizes the function of biobanks in oncology and the requirements for biobank development in translational and clinical research.

**Results.** Biobanks raise numerous ethical issues that government agencies address by enacting particular laws. To develop personalized medicine, biobanks are crucial, given that the availability of an extensive collection of patient samples with thoroughly annotated clinical and pathological data is an essential necessity. Also, data related to biobanking raises complex ethical, legal, and social issues, particularly concerning the protection of donor privacy and the appropriate use of collected samples. International standards have been developed to address these issues to ensure biobanking practices' quality, safety, and integrity.

**Conclusions.** Biobanking is vital in advancing biomedical research, supporting clinical applications, and enhancing our understanding of human health and disease. Using real-world data and biobanking can accelerate medical research, support personalized medicine initiatives, and improve patient care.

**Keywords:** biobank, biospecimen, ethical issues, personalized medicine, oncology

## Introduction

Biobanking refers to systematically collecting, storing, and managing biological samples and associated data for scientific research and medical studies. Biobanking may include human and non-human biospecimens that can be used in biomedical, veterinary and other research fields. Biobanking development created ethical difficulties that have not been fully resolved yet, related to the collecting, preserving, and exchanging of cells, tissues, body fluids, and biodata, including genetic, demographic, and

other forms of information and images, including data anonymization [1,2].

The human biobank database links clinical information, treatment outcomes, and molecular data with stored samples. Researchers can identify specific biomarkers that can be used for diagnosis, prognosis, treatment selection, and monitoring of the therapeutic response [3]. Biobanks should provide the necessary infrastructure to collect and store samples longitudinally, allowing researchers to track changes over time and discover novel biomarkers, but also to support the drug development process

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by developing new therapeutic models such as primary cell lines, organoids and xenografts [4,5].

In the last years, a better understanding of patients' needs was achieved, making them and their association part of the medical decision. Apart from the therapeutic assessment, patients need support on several levels to decide the best clinical options for their cancer. Patients must be fully informed about personalized therapy's potential risks and benefits before they consent to treatment. They must also be aware of the limitations of this technology, including the fact that it is only sometimes effective and may have side effects [6]. Privacy is also a primary ethical concern when it comes to personalized therapy. Patients' genetic information must be kept confidential and secure to protect their privacy. Proper measures must be taken to ensure patients' genetic information is not misused or accessed without their consent [1,7].

The potential for identifying novel biomarkers of disease that provide novel insights into disease etiology, early detection, response to therapy, and monitoring disease progression may be one of the translational research's most intriguing future possibilities for personalized medicine, particularly in the oncology field [8]. Effective clinical biomarker development and discovery are complicated by several factors, such as genetic variation between and within individuals and populations and quantification technologies; another important aspect is the logistical limitations relating to associated costs for the clinical acceptance [8,9].

Personalized therapy uses genetic testing to identify specific mutations or other markers driving the development of a patient's cancer [10]. This allows the development of more targeted and effective treatments that can improve patient outcomes. However, with the effect of personalized therapy come critical ethical considerations that must be addressed to ensure that this technology is used responsibly and ethically [11]. An important implication is the potential for cost savings. Personalized therapy can reduce healthcare costs in the long run by reducing the need for ineffective treatments, side effects, low quality of life and hospitalizations.

These variables can significantly increase the clinical heterogeneity in terms of diagnosis, prognosis, and treatment, which requires access to many biological species collected and processed in standardized conditions to validate novel biomarkers [8]. Despite that, it has proven difficult to identify molecular cancer biomarkers as quantifiable indicators of risk, occurrence, or patient outcome; some of them were already implemented in the clinical management [12]. This is the case of *BRCA1* and *BRCA2* mutations associated with breast and ovarian cancer. The presence of germline variants of genes *EPCAM*, *MLH1*, *MLH2*, *MSH6*, and *PMS2* are related to a higher incidence of colorectal cancer than for pancreatic

cancer [12]. Other actionable genes relate to personalized treatment for specific mutations like EGFR, KRAS and BRAF mutations, ALK, ROS1 and RET rearrangements [13,14].

Medical research aims to develop new protocols and instruments to improve patients' health by orchestrating and sharing extensive multimodal data. Recent studies aim to emphasize the vital role of biobanks in achieving this, emphasizing the critical role of standardization of biobanking approaches to achieve transparent and reproducible research data [2,15].

This is the case of the UK Biobank, which represents an essential resource for cancer research, with deep phenotyping and genomic data [15]. The participants furnish complex clinical data on various factors, physical measurements or multi-modal imaging. The biological samples (blood, serum, plasma, urine and saliva) were collected for long-term storage for a wide range of molecular application [15]. Another interesting project is represented by NAVIGATOR, an Italian regional imaging biobank to encourage the development of precision medicine for oncologic patients based on quantitative imaging and integrative omics analyses [16], notably when correlated with artificial intelligence and complex bioinformatics tools, permitting the development of novel, innovative biomarkers [17].

### Biospecimens processing and data reproducibility

Biospecimens are materials obtained from the human body that can be used to diagnose and analyze cancer, such as tissue, blood, plasma, and other biological fluids (e.g. saliva, seminal *fluid*, vaginal fluids, mucus, urine, cerebrospinal *fluid*, synovial *fluid* or pleural *fluid*) [18].

Biosamples can refer to any biological material collected for scientific research or medical purposes, including tissues, cells, blood, saliva, urine, and others [18]. The life cycle stages of biosamples can vary depending on the specific type of sample and the intended use. Still, generally, the following steps can be identified: (1) collection, (2) processing, (3) storage, (4) analysis, and (5) disposal/restocking [4,9,19] (Figure 1).

The life cycle stages of biobank biological samples are critical for maintaining their integrity, quality, and usefulness for future research. Standardized procedures and careful monitoring of environmental conditions are essential to ensure the long-term viability and stability of the samples. Biobanks must also maintain proper records and tracking of samples to ensure their traceability and prevent contamination. Data must be implemented in electronic records with controlled access from different users. Using biological samples from biobanks has led to significant advances in biomedical research and will

continue to do so in the future for personalized medicine [4,19,20]. An important factor for data reproducibility is related to pre-analytical variability. This refers to the factors that can affect the biospecimens before they are analyzed, such as the collection method, storage conditions, and transportation. Pre-analytical variability can lead to changes in the biospecimen composition, which can impact the accuracy and reproducibility of the data generated. Another challenge associated with biospecimens processing is the processing variability [21]. Processing variability refers to the factors that can affect the biospecimens during the processing steps, such as the type of processing method used, the time between collection and processing, and the conditions during processing. Processing variability can also lead to changes in the biospecimen composition, impacting the accuracy and reproducibility of data generated [22]. At the same time, post-analytical variability is another challenge associated with biospecimens processing. Post-analytical variability refers to the factors that can affect the data

generated after the biospecimens have been analyzed, such as data analysis methods and data interpretation. Post-analytical variability can lead to differences in the results obtained, impacting the reproducibility of data generated [23,24].

Defining the purpose of a biobank and identifying the requirements, particularly those related to funding modalities, is an essential step in its development. The development of a biobank passes through the following phases: defining its purpose, predicting requirements, and obtaining funding. An important issue is the infrastructure and optimization of the preparing techniques based on the already established management system implementation and initial operations. The latest international tendency related to biobanks is to function as a network, permitting them to maximize their potential on both the national and international levels [18]. Collaboration enhances the statistical power of studies, validates findings across different populations, and accelerates the translation of research discoveries into clinical applications.



**Figure 1. The Roadmap of Biobanking for oncology patients as a sustainable pipeline encompassing multiple stages.** This includes the collection of samples from biobank participants and a signed informant consent (*step 1*), collecting, processing and storage of biospecimens (*step 2*), distribution of samples for analysis (*step 3*), and then integration of the experimental and clinical data in an integrative mode for research progress (*step 4*). This will enhance our understanding of disease to promote advancing research that will permit the development of novel biomarkers or therapeutic strategies (*step 5*).

**Table I.** The life cycle steps of biosamples for personalized medicine.

Step	Role	Reference
Collection	Biosamples are collected from donors or patients through various methods, such as biopsy, blood draw, or saliva swab, in a sterile and consistent manner to avoid contamination or degradation	[4,19,26]
Processing	Processed to extract specific components or prepare them for analysis; separating cells from tissues, isolating DNA or RNA, or freezing the samples for long-term storage.	[4,26]
Storage	Can be stored for various periods (ranging from a few hours to several decades). Proper storage conditions are critical to ensure sample integrity and avoid degradation or contamination. Depending on the sample type and storage duration, different storage methods, such as refrigeration, freezing, or cryopreservation, may be used	[4,19,26]
Analysis	Biosamples are typically analyzed to answer research questions or diagnose medical conditions. This may involve various techniques, such as microscopy, genomics, proteomics, or metabolomics, depending on the specific research question and sample type are some specific requirements related to quality control for samples.	[4,9,26]
Disposal/ Restocking	Once the analysis is complete, biosamples may be disposed of in a proper and ethical manner. This may involve autoclaving, incineration, or chemical treatment, depending on the sample type and any associated hazards.	[4,9,26]

A document was launched in 2018 by the International Organization for Standardization (ISO) related to the main requirements for biobanking (ISO 20387:2018) [25] (ISO (2018) International Standard ISO 20387:2018 - Biotechnology - Biobanking - General requirements for biobanking, First Edit. <https://www.iso.org/standard/67888.html>). Thus, the biobank is defined as legal entities or parts of a legal entity. A biobank is an organization that gathers, refines, preserves and provides access to biospecimens. Therefore, it implies collecting, processing, storing, and distributing biospecimens and relevant clinical data. The coexistence of biological specimens with associated data, such as relevant personal information like family history, lifestyle and genetic information, is mandatory for research purposes [25]. This information is summarized in table I.

**Biobanks in personalized medicine**

Biobanks provide researchers access to a diverse range of patient samples, enabling the study of disease heterogeneity and the development of personalized treatment strategies. The effect of customized therapy in oncology has far-reaching implications for patients, clinicians, and society. At the same time, critical ethical perspectives must be considered as we move forward with this technology supporting the scientific progress in population stratification, biomarker discovery and validation [27].

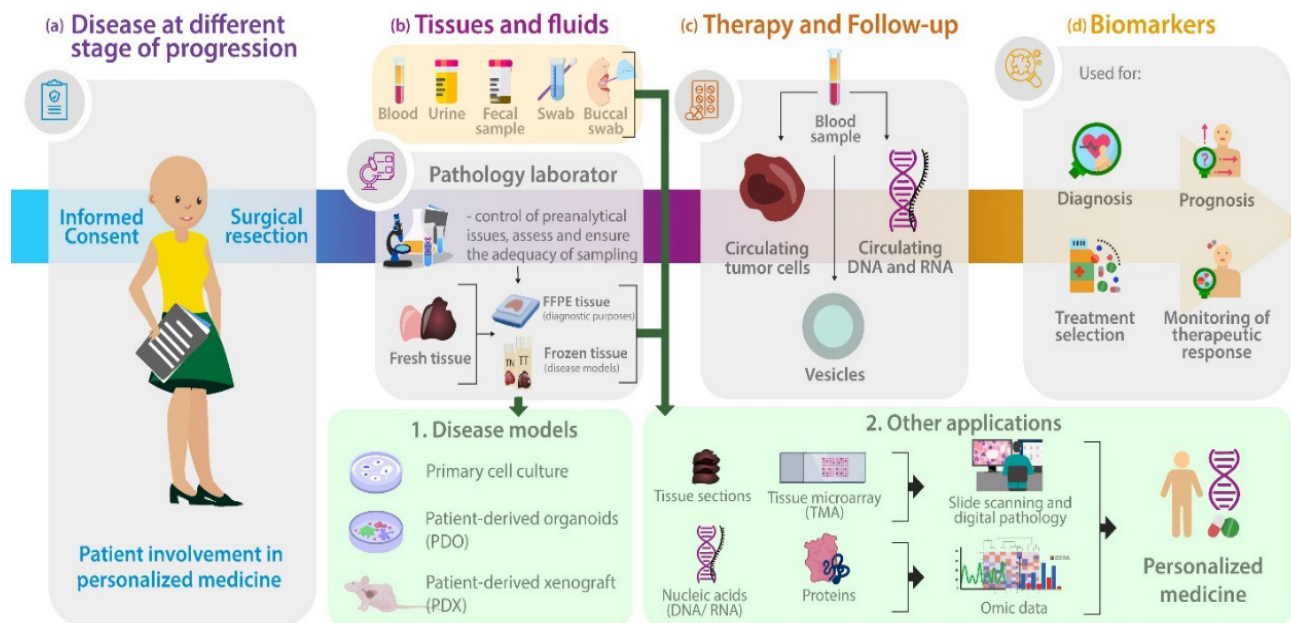
Before clinical trials, biobank samples can also be utilized in preclinical studies to evaluate the effectiveness of new drugs or treatment combinations. Biobanks support clinical trials by providing researchers with well-characterized samples from patients with specific diseases

or conditions [28]. These samples can identify eligible patients for clinical trials, stratify patients based on their molecular profiles, and monitor treatment response. Biobanked samples can also be utilized to validate findings from preclinical studies and support the translation of promising therapies into clinical practice [5].

One significant implication of personalized therapy is that it has the potential to revolutionize oncological treatment. Clinicians can be helped by personalized medicine to identify specific mutations or other markers that drive the growth of a patient’s cancer through a patient’s genetic makeup. This can lead to more targeted and effective treatments and better patient outcomes. However, there are also ethical implications to consider. One of the biggest concerns is access to personalized therapy. While it can improve patient outcomes, it is often expensive and not covered by insurance. This means that only those who can afford it may be able to benefit from this technology, creating disparities in care. Biobanks collect associated clinical and molecular data, such as patient outcomes, treatment responses, and genetic information. These data relate to each patient’s biobank file, providing researchers with valuable information for correlating biological features with clinical outcomes and advancing the translational research [28].

Primary cell lines are derived directly from patient tissues and represent the characteristics of the original tumor or tissue. Biobanks collect and store these primary cell lines, ensuring their preservation and availability for future research and therapeutic development. By providing researchers with access to well-characterized and authenticated primary cell lines, biobanks contribute to developing new therapies and drug testing platforms.





**Figure 2. Role of biobanks in personalized medicine in oncology.** (a) Assuming the patient has given informed consent (a), various biological specimens can be collected (fluids such as blood, urine, fecal sample, swab, buccal swab, and fresh tissue from surgical resection) (b). Pathologists are crucial in ensuring appropriate sampling without affecting the final diagnosis. Surgical specimens, mainly frozen tissue, can create disease models such as primary cell culture, PDO, and PDX (1). The biological fluids and tissue (FFPE and frozen tissue) can be used for high-throughput genomic analyses that undergo personalized medicine (2). Moreover, tissue and blood samples (including circulating tumor cells and vesicles) can be extracted nucleic acids and proteins (c) to help identify specific biomarkers that can be used for diagnosis, prognosis, treatment selection, and monitoring of therapeutic response.

Organoids are three-dimensional cell cultures that mimic the structure and function of specific organs or tissues [3,28]. They are generated from stem cells or tissue-derived cells. Biobanks may store organoid cultures derived from patient samples, preserving them for the study of disease mechanisms, drug screening, and personalized medicine [28]. Organoids derived from biobank tissues can serve as valuable models for understanding tumor biology and testing therapeutic responses [3,5].

Xenograft models involve the transplantation of patient-derived tumor tissues into immunocompromised mice. Biobanks can collect and store patient tumor samples, including tumor fragments or cells, which can be later used to establish xenograft mice. These models enable researchers to study tumor growth, metastasis, and drug response in more *in vivo* models. Biobank samples provide a continuous source of material for establishing and maintaining xenograft models (Figure 2).

### Biospecimen quality control

Biobanks have become increasingly popular in recent years as they provide a valuable resource for scientific research. However, the quality of the specimens in biobanks is critical for the success of research studies, as the integrity of the samples can impact the accuracy and reproducibility

of the data generated [29]. Quality control measures are essential to ensure that the samples stored in biobanks are high quality and suitable for use in research. These measures involve collecting, processing, and storing samples under standardized conditions using standardized protocols to ensure that the samples are stored at the correct temperature and humidity to prevent degradation [30]. Moreover, the sample should be periodically tested to determine their purity and integrity and ensure that the samples are not contaminated with other biological materials [18].

Human biospecimens used for personalized medicine in oncology imply the use of high-quality samples agreeing with strict ethical and procedural guidelines [29]. Yet, a wide range of techniques are used to collect, stabilize, process, and store biospecimens for study, and the quality of the biospecimen frequently needs to be discovered [26]. A critical aspect of biospecimen processing is using standardized protocols to ensure that samples are processed consistently across different studies [31]. This includes using the same equipment, reagents, and procedures to minimize variability and increase reproducibility. Biospecimens should be quickly processed after collection to prevent samples' degradation and maintain the integrity of biological molecules, such as DNA, RNA, and proteins [32].

Another critical component of biospecimen processing is using quality control measures to ensure that samples meet specific standards. This includes assessing the quantity and quality of DNA, RNA, and proteins in samples and ensuring that samples are free from contamination and other issues affecting data reproducibility [31,32].

Researchers have developed guidelines for data sharing and analysis to promote data reproducibility. This includes making data and analysis code available to other researchers, using statistical methods that are transparent and replicable, and conducting sensitivity analyses to assess the robustness of findings. Similarly, by promoting data sharing and transparent investigation, researchers can increase the transparency and robustness of research findings, which can help guide clinical practice and policy decisions [31].

### **Biospecimens and intellectual properties**

Intellectual property (IP) refers to legal rights granted to individuals or organizations for their inventions, creations, or innovations. It encompasses various forms, such as patents, copyrights, trademarks, and trade secrets. IP protection is intended as an incentive for innovation, allowing creators to benefit from their work [33].

When researchers use biological specimens obtained from biobanks to make discoveries, there may be potential implications for IP rights. For example, if a new diagnostic test or therapeutic product is developed based on research involving biobank samples, IP rights may be sought to protect the invention. This can include patenting specific genes, biomarkers, or processes involved in the discovery. It's worth noting that obtaining IP rights in the field of genetics and biological research can be complex due to evolving legal and ethical considerations [4,33].

Biobanks often have guidelines and policies regarding access to their collections and associated data. Balancing access to research while respecting patient privacy and ethical considerations is crucial. Some biobanks may require researchers to adhere to data-sharing agreements or obtain informed consent from participants for specific research purposes. These agreements may include provisions related to IP rights and the commercialization of any discoveries made [33].

The legislation related to biobanking and IP is governed by the various national directives that local government has set (data protection rules), and technically speaking, the multiple techniques for collection, informed consent, anonymization, storing, and primary clinical data have led to a considerable degree of variation between biobanks [20]. These elements might obstruct the overarching objective of a global research framework that seeks to ease access to human biological materials. A

significant source of variation occurs from the biosamples' life cycle stages, which are defined as the collection, accession, acquisition, identification, preservation, long-term storage, quality control (QC), transit, and disposal of biomaterials [26,34].

### **Biospecimen procurement and related ethical issues**

Biobanking activities raise unanswered ethical questions about the collection, storage, and sharing of cells, tissues, bodily fluids, and biodata, including genetic, demographic, and other types of information and images. In addition to human materials, biobanking involves non-human materials that might be used in human, veterinary, agricultural, ecological, and other research and health care. A feature of most biobanks is that samples and data are collected for long-term future applications, not just for a single project [35].

Biobanking has been implemented as a routine in health care, research, and public health emergencies; however, the associated governance standards must be more consistent and sometimes missing globally. Biobanking accreditation is a process that ensures that biobanks meet established standards for sample and data quality, ethical, legal, and social issues, and scientific performance. However, ethical issues related to biobanking accreditation requirements can arise, and they need to be addressed to maintain public trust and confidence in biobanking activities. The complexity and breadth of biobanking practices generate risks, benefits, and responsibilities that need to be adequately identified or resolved [36].

There is an assumption that biobanking is low risk and that de-identifying materials provide enough protection to donors when materials are collected, stored, exchanged, transferred, or analyzed. Materials contributed to a biobank can be identified by genetic tests or through big data gathered from social media, smartphones, wearables, sensor applications, and more. They allow for the exchange and analysis of individual and group data and its commercial and healthcare applications.

An essential step for sample collection, stored, shared, transported, or studied biomarkers is data anonymization when requiring de-identifying patients for follow-up studies to furnish suitable protection to donors.

One ethical issue related to biobanking accreditation requirements is the informed consent process. Informed consent from donors must be obtained before collecting and storing their samples and data. Thus, the purpose, nature, benefits, and risks must be presented to the donors and their voluntary participation agreement. Furthermore, biobanks must ensure the ethical obtaining of informed consent and that donors understand the potential uses and

implications of their samples and data [6].

Informed consent is a critical component of biobanking facilities, involving all steps previously identified. Obtaining informed consent complies with the individual understanding of the biobank nature, the potential risks and benefits of their participation and when and how their samples will be used. Patients' informed consent in personalized oncology must be obtained before initiating any procedure or medical intervention/therapy involving personalized medicine tools. By obtaining informed consent, healthcare providers can uphold patient autonomy, respect privacy rights, and foster trust between the patient and the healthcare team. It allows patients to actively participate in their care and make informed decisions about personalized treatment options in personalized oncology.

Personalized medical procedures are based on specific features of each patient and the disease, including genomic profiling, environmental factors, lifestyle, and other particular characteristics. Informed consent is a fundamental ethical and legal requirement to ensure patients obtain all the information regarding their disease to decide their level of care independently. Personal data, genetic and genomic testing, and targeted treatments are important topics in personalized cancer medicine.

### Accreditation of biobanks

Biobanking accreditation aims to ensure that biobanks maintain high standards of quality and ethical practices and requires accession to specific requirements

that govern different aspects of their activities, such as management, storage, and distribution of biospecimens, as well as the collection and use of associated data. However, implementing these accreditation requirements has raised several ethical issues that need to be addressed, summarized in the new ISO 20387:2018 [34]. Another relevant example related to specific standards is presented in table II.

Accreditation requirements for biobanks aim to ensure that they operate ethically and effectively. Accreditation is a process in which an independent organization assesses whether a biobank meets specific standards, such as those related to ethical, legal, and social issues. The measures ensure that the biobank respects individuals' rights and privacy, obtains informed consent, and uses the samples and data for research purposes consistent with the donors' wishes [4,37].

Informed consent is the process by which individuals are provided with information about the biobank's purpose, procedures, risks, and benefits and can decide whether to donate their biological samples and associated data. Biobank accreditation requirements mandate that informed consent be obtained, but the specific requirements vary among different accreditation bodies. Some require written consent, while others accept verbal or implied consent. Additionally, some require that the consent be obtained directly from the donor, while others allow for proxy consent, such as from a family member or legal guardian [38].

**Table II.** Examples of standards for biobanking.

Standard	Description	Reference
ISO 20387:2018	This standard specifies general requirements for biobanking of biological materials and related data, including the quality management system, data management, and ethical considerations.	[34]
ISO 17025:2017	This standard specifies the general requirements for the competence of testing and calibration laboratories, including biobanking laboratories. It covers the requirements for equipment, personnel, methods, and quality control.	[40]
OECD Best Practice Guidelines for Biological Resource Centres	The Organization for Economic Co-operation and Development (OECD) has established a set of best practice guidelines for biological resource centers, including biobanks. The guidelines cover ethical and legal considerations, quality management, and data management.	[40]
Global Alliance for Genomics and Health (GA4GH)	The GA4GH is an international consortium of researchers, healthcare providers, and industry partners working to develop a common framework of standards for genomic and clinical data sharing. They have developed guidelines for biobanking, including ethical considerations, data sharing, and informed consent.	[41]
European Research Infrastructure for Translational Medicine (EATRIS)	Pan-European infrastructure that aims to accelerate the development of new medicines by providing a platform for translational research. They have developed a set of guidelines for biobanking, including ethical and legal considerations, quality management, and data sharing.	[42]

Another ethical issue related to biobanking accreditation requirements is data privacy and confidentiality. Biobanks must ensure that donors' identities and personal information are protected and that their samples and data are used only for approved research purposes. Biobanks must also have strict data security measures to prevent unauthorized access, use, or disclosure of donors' samples and data. Also, the biobanks must ensure donors' samples and data are used to respect their interests, values, and preferences. Donors should have a say in how their samples and data are used, and ethical and legal frameworks should protect their rights. Biobanks must also consider the interests of research participants, communities, and society when making decisions about sample and data use [38,39]. The patients' clinical and genetic information must be kept confidential and secure to protect their privacy. Proper measures must be taken to ensure patient data is not misused or accessed without their consent [38].

Biobanks must ensure their activities are transparent and accountable to donors, research participants, communities, and society. Biobanks must have clear policies and procedures for sample and data collection, storage, use, and disposal. Biobanks must also possess the mechanisms to address legal, ethical and social issues related to their activities and involve stakeholders in decision-making.

The accreditation requirements for biobanks are crucial to ensure biobanking activities' legal, ethical, and social issues and scientific performance. However, ethical issues related to biobanking accreditation requirements

can arise, and they need to be addressed to maintain public trust and confidence in biobanking activities. Biobanks must ensure that informed consent is obtained ethically, that the donors' identities and personal information are protected, that donors' samples and data are used to respect their interests, values, and preferences, and that their activities are transparent and accountable to stakeholders. By addressing these ethical issues, biobanks can be vital in advancing biomedical research and improving public health [38].

### AI role in biobanking

Biobanks generate vast amounts of data, including genomic, proteomic, and clinical information associated with stored samples [43,44,45]. Biobanking and artificial intelligence (AI) can be synergistic and mutually beneficial in several modes, presented in table III, to support real-world data for personalized medicine. By combining diverse data types, AI can be helpful in the discovery of novel biomarkers, genetic pathways, and therapeutic targets, driving advancements in the cancer research [43]. Also, AI can be used for personalized treatment selection, dosage optimization, and the prediction of adverse drug reactions, improving patient outcomes. AI algorithms, and intense learning techniques, can analyze these images to assist in automated image recognition, classification, and quantification of various tissue features; they also can generate powered models that can simulate drug interactions, and toxicity profiles and identify optimal patient populations for clinical trials, aiding in more efficient and targeted drug development processes [46].

**Table III.** Application of AI in biobanking for personalized medicine.

Application	Observation	Reference
Data Management and Analysis	AI algorithms can be applied to efficiently manage and analyze these complex datasets. AI-powered data analysis tools can identify patterns, correlations, and predictive models, leading to insights and discoveries that may not be readily apparent through traditional analysis methods.	[43,44,45,46]
Precision Medicine and Treatment Prediction	AI algorithms can analyze the diverse molecular and clinical data available in biobanks to identify biomarkers, predict treatment responses, and tailor therapies to individual patients	[43,46]
Image Analysis and Pathology	AI algorithms, particularly deep learning techniques, can analyze these images to assist in automated image recognition, classification, and quantification of various tissue features	[43]
Data Integration and Knowledge Discovery	AI can facilitate the integration and analysis of these heterogeneous datasets, uncovering hidden relationships, and generating new hypotheses.	[43,46,48]
Predictive Modeling and Drug Development	Biobanks, coupled with AI, can support predictive modeling for drug development. AI algorithms can analyze molecular data from biobank samples to predict drug responses, identify potential drug targets and accelerate the discovery and development of new therapies.	[43,49]
Data Privacy and Security	Enhance data privacy and security-AI algorithms can be utilized to develop robust data de-identification techniques, ensuring that patient identities are protected while maintaining the utility of the data for research purposes. AI-powered security systems can also detect and mitigate potential data breaches, safeguarding the confidentiality of biobank data.	[43]
Clinical Decision Support Systems	Personalized treatment recommendations predict treatment outcomes and suggest potential clinical trials or targeted therapies based on the analysis of biobank data.	[43,47]



AI technologies can be integrated with biobank data to develop clinical decision support systems. By incorporating patient-specific molecular and clinical data, along with AI algorithms, these systems can assist healthcare professionals in making informed treatment decisions [43,44,46,47]. For example, Research Electronic Data Capture (REDCap) was used to develop rules that generate an output representing a set of recommendations to the clinician [47].

Integrating biobanking and AI technologies holds great potential to accelerate research, enable precision medicine, improve diagnostics and advance drug development in oncology. Combining high-quality biobank samples and AI-driven analysis can unlock valuable insights and empower researchers and clinicians to make more informed decisions for better patient outcomes.

The use of AI for generating real-world data and biobanking has the potential to accelerate medical research, support personalized medicine initiatives, and improve patient care. However, it also raises important ethical and privacy considerations. Safeguards must be in place to protect individuals' privacy and ensure the responsible and ethical use of their data and samples. Legal and regulatory frameworks governing data protection and informed consent play a crucial role in maintaining public trust and ensuring the appropriate use of real-world data and biobanking resources.

### Conclusions and perspectives

The presented data emphasize the critical role of personalized medicine in developing novel therapeutic strategies in oncology. But at the same time, we should raise some concerns about ethical issues related to healthcare disparities between developed and low-income countries. High professional standards must be upheld in managing biobanks, and the significance of sufficient financing, education, and certification must be highlighted. Biobanks will be able to collaborate because of the expanding presence of both national and international biobank networks. The growth of a biobanking community will promote collaboration to address shared obstacles and improve communication with various stakeholder groups.

To meet the demands of customized medicine, biobanking services must advance quickly, and biospecimen research should be encouraged and supported at all levels, from project funding through the publication of findings.

Biobanking facilitates the development of new therapeutic models by providing researchers access to patient-derived samples and associated data. These resources allow researchers to study disease biology, identify biomarkers, drive drug discovery, and develop personalized treatment approaches. Biobanks represent

an essential infrastructure for advancing research and improving patient care in various fields, including oncology and other areas of medicine.

The convergence of biobanking and AI holds immense potential for advancing personalized medicine. AI-driven analysis of biobank data enhances the understanding of disease biology, enables the discovery of new biomarkers and drug targets, and supports precision medicine approaches. Ultimately, integrating AI technologies with biobanking practices can revolutionize healthcare by improving patient outcomes and accelerating the development of innovative therapies.

In conclusion, the development of personalized therapy in oncology has the potential to improve patient outcomes significantly. Still, it is essential to consider the ethical implications of this technology as we move forward. We can ensure personalized therapy is used responsibly and ethically by addressing access, informed consent, privacy and equity concerns.

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