

How to Cite:

Alkhathami, A. A., Alqahtani, Bakr M., Hadadi, A. M., Alhussain, A. H., Alquwayi, W. A., Alkuwaiti, Y. A. A., & Almeahiny, A. M. (2021). Biobanking and its role in clinical research and pathology. *International Journal of Health Sciences*, 5(S1), 1289–1305.
<https://doi.org/10.53730/ijhs.v5nS1.15206>

Biobanking and its role in clinical research and pathology

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Abstract--Background: Biobanks have gained recognition for their crucial role in clinical research and pathology, particularly in advancing precision medicine. Their evolution from traditional to virtual biobanks marks a significant shift in biomedical research methodology. **Aim:** This article examines the development, significance, and operational aspects of biobanks, highlighting their role in personalized medicine and the challenges they face. **Methods:** A comprehensive review of literature and established guidelines was conducted to analyze the characteristics, classifications, and governance of biobanks, with a focus on their infrastructure and data management. **Results:** Biobanks, both physical and virtual, provide invaluable resources for molecular and genetic epidemiology, molecular pathology, and pharmacogenomics. They enable researchers to conduct large-scale studies, identify biomarkers, and tailor treatments to individual genetic profiles. However, significant

challenges exist, including ethical concerns, funding, and the need for robust governance structures. **Conclusion:** Biobanks represent a vital component of modern biomedical research, facilitating advances in personalized medicine. While they offer immense potential, addressing infrastructural and ethical challenges is essential for their sustainability and effectiveness in improving health outcomes.

Keywords--Biobanks, precision medicine, clinical research, virtual biobanks, molecular pathology, ethical considerations.

Introduction

In 2009, *Time* magazine included biobanks among the “10 Ideas Changing the World Right Now,” emphasizing their potential for researchers to glean insights from vast collections of samples [1]. Initially focused on cancer, biobanks were seen as a promising avenue for screening and treating a wide range of diseases [1]. Over the past decade, biobanking has experienced significant growth alongside the rise of precision medicine. *Forbes* has also addressed the critical role biobanking plays in personalized medicine [2], noting the transition from traditional collections of tissues, blood, nucleic acids, microbiomes, and stem cells to the development of virtual biobanks. This evolution prompts concerns regarding whether there is sufficient infrastructural and financial backing to sustain the rapid progress of biobanking. The International Agency for Research on Cancer (IARC) asserts that biobanks now underpin three rapidly advancing areas of biomedical research: (i) molecular and genetic epidemiology, which seeks to understand the genetic and environmental factors contributing to cancer in both populations and families, (ii) molecular pathology, which focuses on creating molecular-based cancer classifications and diagnostic tools, and (iii) pharmacogenomics and pharmacoproteomics, which aim to explore the link between a patient’s genotype or phenotype and their response to drug treatments [3].

Virtual Biobanks:

Virtual biobanks are digital repositories that store, manage, and provide access to data derived from biological samples, rather than the physical samples themselves. Unlike traditional biobanks, which involve the collection and storage of physical biospecimens such as blood, tissues, and DNA, virtual biobanks focus on the digitized information extracted from these samples, such as genetic data, clinical records, and metadata.

Key Features of Virtual Biobanks:

1. **Data-Driven:** Virtual biobanks primarily handle large datasets, including genomic sequences, proteomic data, and other biological information.
2. **Accessibility:** Researchers can access, share, and analyze data from anywhere in the world without the need for physical transfer of samples.

3. **Cost and Space Efficiency:** Since physical storage is minimized, virtual biobanks reduce the cost of maintaining biological samples and require less infrastructure.
4. **Enhanced Collaboration:** Virtual platforms enable global collaboration by making data available to multiple research institutions.
5. **Privacy and Security:** As with any digital platform, virtual biobanks must implement strict data security and privacy measures to protect sensitive genetic and health information.

Examples of Virtual Biobanks:

- **Genomic Databases:** Repositories like the 1000 Genomes Project or the UK Biobank make genetic data available for research without physically transferring samples.
- **Cloud-Based Systems:** Virtual biobanks often use cloud storage to hold large-scale datasets, which can be queried and analyzed remotely.

These biobanks are crucial in advancing precision medicine, allowing researchers to analyze vast amounts of data to identify biomarkers, understand disease mechanisms, and develop personalized treatments.

Biobanks: Definitions and Key Characteristics

Although the term "biobank" was first introduced in scientific literature in 1996 [4, 5], a universally accepted definition has yet to be established. Over time, the term has been widely adopted to refer to collections of biospecimens or human genetic data that can be utilized for research [6]. One of the initial definitions, proposed by the Organization for Economic Cooperation and Development (OECD), described biobanks as "a collection of biological material and the associated data and information stored in an organized system, for a population or a large subset of a population" [5, 7]. This definition was later refined to refer to biobanks as "structured resources used for genetic research, which include (a) human biological materials and/or data generated from their analysis, and (b) extensive associated information" [8].

A fundamental aspect of biobanking is the integration of biological specimens with their corresponding data. Biobanks consist of large repositories of human biological materials linked to personal and health information, such as medical records, family histories, lifestyle details, and genetic data, which are primarily intended for health and medical research [6, 9] (Fig. 1). According to the International Organization for Standardization (ISO), which outlines general requirements for biobanking (ISO 20387:2018), biobanks are defined as legal entities or parts of legal entities that engage in biobanking activities. These activities include the acquisition, storage, and associated processes like collection, preparation, preservation, testing, analysis, and distribution of biological material and related data [10].

To accommodate advancements in biotechnology and the life sciences, the concept of Biological Resource Centres (BRCs) was introduced by OECD. These infrastructures consist of service providers and repositories for living cells, organism genomes, and information about heredity and biological functions [11].

Based on these definitions, the distinction between biobanks and other research collections can be somewhat ambiguous [6]. However, the European Commission emphasizes that biobanks are specifically dedicated to collecting biological samples and associated data for medical and scientific research, systematically organizing these for diagnostic purposes [12]. Additionally, a key differentiating feature of biobanks is their established governance mechanisms, which facilitate access to resources for external researchers in a systematic manner [12, 13, 14].

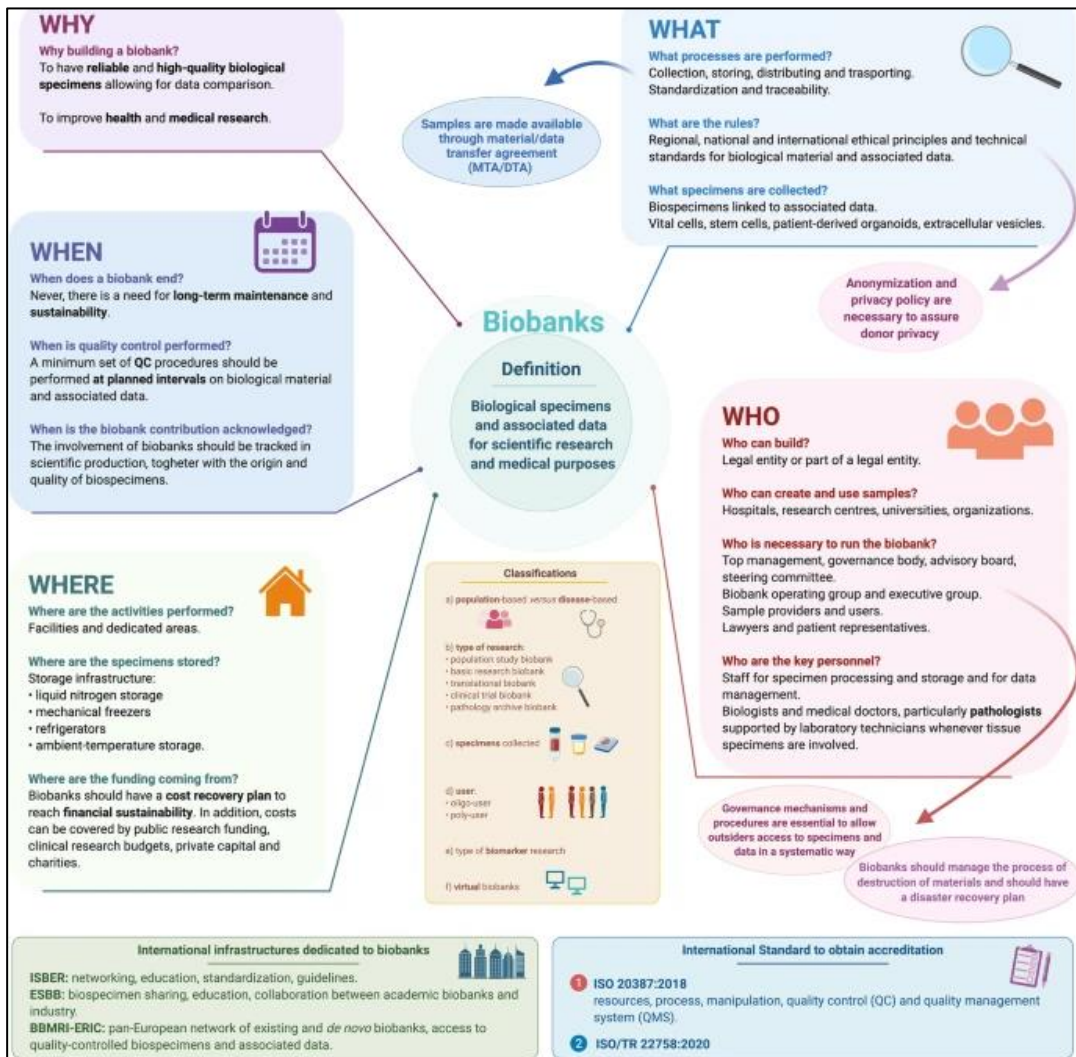


Figure 1: Fundamental principles of biobanking involve structuring information using the 5Ws approach (why, what, who, where, and when).

This method highlights the definitions, classification systems, essential elements, international standards necessary for accreditation, and the infrastructures required to guarantee quality and facilitate networking.

Both biorepositories (ISBER 2001) and BRCs (OECD 2007) may contain human and animal tissues, as well as cell and bacterial cultures, and even environmental samples. However, biobanks typically focus on handling human biospecimens along with donor information, such as demographic and lifestyle details, medical history, treatments, and clinical outcomes. Given the diverse purposes and backgrounds of biobanks, it is challenging to define a single set of characteristics that apply to all. Nonetheless, according to the European Commission, biobanks generally:

- (i) Collect and store biological materials that are annotated with medical and, often, epidemiological data (e.g., environmental exposures, lifestyle/occupational information).
- (ii) Are not static entities, as biological materials and data are often gathered continuously or over extended periods.
- (iii) Are linked to both current (defined) and future (unspecified) research projects at the time of biospecimen collection.
- (iv) Employ coding or pseudonymization to ensure donor privacy, while still allowing for donor reidentification under certain conditions to provide clinically relevant information.
- (v) Maintain governance structures and procedures designed to safeguard the rights of donors and the interests of stakeholders [12].

Moreover, biobanks prioritize public benefit over individual participant gains, aiming to contribute to the public good for future generations through the application and translation of research findings [6, 9].

It is important to note that biological samples are "pseudonymized," rather than completely "anonymized." This distinction is crucial as it enables the possibility of providing feedback to the sample owners, gathering additional valuable information, and reconnecting it to the original specimens.

Classification Systems

Currently, there are no universally accepted guidelines for classifying biobanks, but establishing a comprehensive classification system would assist researchers in locating specific biospecimens. Biobanks are inherently diverse, varying in size, research focus, participant health status, specimen types, sample collection methods, and storage systems [6, 12] (Fig. 1). A preliminary classification divides biobanks into "population-based" and "disease-oriented" categories (Fig. 1): Population-based biobanks collect specimens from a general population to investigate how genetic susceptibility and environmental exposures contribute to specific diseases by linking molecular data to other relevant information [15]. Disease-oriented biobanks focus on collecting biospecimens related to particular diseases, which may include samples from various sources linked to a specific condition, such as cancer [15, 16].

Malsagova and colleagues noted that large-scale epidemiological studies or collections from clinical trials can also form biobanks [17]. Therefore, biobanks may be classified based on the type of research they support:

- (i) Population study biobank
- (ii) Basic research biobank
- (iii) Translational study biobank
- (iv) Clinical trial biobank

- (v) Pathology archive biobank [18].

Additionally, some researchers categorize biobanks according to opportunities for biomarker discovery [19]:

- (i) Population biobanks (biomarkers of genetic susceptibility and identity)
- (ii) Disease-oriented and epidemiology-driven biobanks (biomarkers of exposure and biological effects)
- (iii) Disease-specific biobanks, such as tumor banks [19].

Another classification method focuses on the types of samples collected, such as frozen tissues, formalin-fixed paraffin-embedded (FFPE) tissues, cells, whole blood, urine, buccal cells, saliva, bone marrow aspirate, and nucleic acids (DNA, RNA, cDNA/mRNA, microRNA) [3, 15]. Watson and Barnes proposed a schema, later adopted by the Canadian Tumour Repository Network (CTRNet), which categorizes biobanks by four functional elements: donor type, collection methods and design (e.g., retrospective or prospective), specimen preservation type (e.g., fixed or frozen), and intended users (e.g., single institution or multiple users) [18, 20]. Lastly, there is the concept of virtual biobanks, which are electronic repositories of biological samples and related data, regardless of where the physical specimens are stored (Fig. 1) [16, 17, 21]. For a practical overview of available biobanks in Europe and their sample types, researchers can refer to the Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium (BBMRI-ERIC) directory [22, 23]. As of 2011, this directory included 63 population-based and 219 clinical biobanks, growing to 515 biobanks representing over 60 million biological samples [22, 24].

Biobanks can operate within hospitals, research centers, pharmaceutical companies, or patient advocacy organizations. Academic biobanks, typically supported by institutional funding and grants, are research-driven. In contrast, industry biobanks tend to be product-focused and business-oriented [25]. Despite their differences, both sectors must recognize that human specimens and data are not mere commodities, but part of scientific endeavors involving human subjects [25]. Moreover, as personalized medicine advances, biobanks should adopt a patient-centered approach [26]. The Patient-Centered Outcomes Research Institute (PCORI) has created pathways to fund patient-focused research, aiming to make research findings more applicable in healthcare decisions [27, 28].

An example of patient-centered biobanking is the PATH Biobank (Patients' Tumor Bank of Hope) in Germany, a non-profit organization founded by breast cancer survivors to support research in both academic and industrial contexts. This model exemplifies the evolving role of patients in biobanking, transitioning from passive donors to active participants [26]. Interestingly, PATH Biobank allows leftover samples to be divided: one part remains with the patient, while the other is used for research. Upon the patient's death, the sample becomes PATH property, available for future research [29].

Key Considerations for Establishing a Biobank

The establishment of a biobank is a complex endeavor that presents numerous challenges related to the handling and management of biospecimens (Fig. 1).

Harati et al. (2017) outlined essential guidelines for biobank creation, addressing aspects such as accreditation, adherence to standards of practice, and funding considerations [16]. A guidance document from the South Australian government emphasizes the importance of having a clear purpose or business plan, along with careful attention to governance, funding, data management, specimen oversight, and informed consent processes [9]. Furthermore, obtaining accreditation and complying with established standards allows biobanks to function effectively and ensures that they provide biological specimens of sufficient quality [17].

Prioritizing ethics, privacy, informed consent, data security, and standardization is critical (Fig. 1). According to the International Agency for Research on Cancer (IARC), the development of biobanks is intertwined with ethical, legal, and social issues (ELSI) and necessitates the establishment of robust governance structures [3]. The recommendations from IARC are informed by various initiatives, including the Standardization and Improvement of Generic Preanalytical Tools and Procedures for In Vitro Diagnostics (SPIDIA), the BBMRI – Large Prospective Cohorts (BBMRI-LPC), and the International Genomics Consortium (IGC), as well as standards set by the European Committee for Standardization (CEN) and the International Organization for Standardization (ISO) [3].

The IARC identifies several critical elements to consider when establishing a biobank:

- Types, quantities, aliquots, and sizes of biospecimens
- Storage containers
- Storage temperature and conditions
- Frequency of access to biospecimens
- Requirements for biospecimen identification
- Availability of storage space
- Temperature monitoring requirements
- Associated data
- Financial and operational sustainability [3].

Additionally, the IARC document offers protocols for sample processing and templates for consent forms and material/data transfer agreements (MTA/DTA) [3, 30]. A vital factor in the establishment, reliability, and sustainability of a biobank is the standardization of procedures related to sampling, storage, and quality control (QC). Recent years have seen targeted efforts aimed at standardizing preanalytical, analytical, and postanalytical processes in scientific laboratories, including biobanks. The SPIDIA project, initiated by the European Union's FP7 program in 2008, engaged prominent academic institutions, international organizations, and life sciences companies to enhance the standardization of preanalytical procedures for in vitro diagnostics. This initiative resulted in the creation of nine CEN Technical Specifications (CEN/TS) for preanalytical workflows in Europe. In 2017, the SPIDIA4P project expanded upon these findings to develop and implement an additional 14 pan-European preanalytical CEN/TS and ISO/IS documents, along with external quality assessment schemes (EQAs), to improve preanalytical workflows for personalized medicine. The SPIDIA4P initiative has been recognized as one of three success stories by the European Commission.

Information technology (IT), data management systems, and record administration represent crucial components of biobanks. It is essential to ensure that these elements operate effectively and securely [16]. Successful biobank implementation requires a robust sample traceability system, particularly through the use of barcoding and an IT platform that integrates seamlessly with all institutional systems to automatically compile data, thereby minimizing errors associated with manual entry. Biobanks must guarantee not only the traceability of biological materials and associated data but also their destruction when necessary [10]. They should have mechanisms in place to manage the destruction of biological materials and/or the deletion of associated data, ensuring irreversible removal. A legacy plan is recommended to clarify the protocols for the transfer or destruction of specimens and associated data in the event of specific occurrences [31]. Ethically, the destruction of samples post-consent is generally not stipulated in informed consent documents, as biobanks traditionally inform participants that their samples will support future biomedical research initiatives. To maintain transparency, biobanks should incorporate appropriate disclosures regarding the potential destruction of specimens in their consent forms, as safeguarding the interests of donors is a fundamental responsibility [31].

Finally, biobanks should develop disaster recovery plans to prevent the loss of biological materials due to natural or human-induced disasters [3, 10, 32]. The IARC document provides comprehensive guidance on formulating recovery plans, outlining key steps such as prioritizing samples, detailing actions through standard operating procedures (SOPs), and ensuring backup storage for sample transfers [3].

Financial and Operational Sustainability of Biobanks

Biobanks require financial resources for their establishment, personnel management, and ongoing operational support (16). Recent findings from the National Cancer Institute's Biorepositories and Biospecimen Research Branch highlight that most biobanks lack strategies for long-term sustainability; they predominantly rely on public research funding and are often not independent from their host institutions, which typically depend on publicly funded research initiatives (33). Despite biobanks investigating various funding avenues—including extramural and intramural financing from private investors, government sources, and philanthropic organizations—achieving sustained financial viability remains challenging. Data regarding cost recovery indicates a troubling trend, as many biobanks recoup negligible fees relative to their operational expenditures (34). An international panel of experts has developed a framework for pricing access to biospecimens and associated data (35). Tested among 16 European biobanks, this experience demonstrated that financial sustainability is feasible only if biobanks adopt a cost-recovery policy predicated on user fees that accurately reflect their operational costs (35). An effective economic model should align with market demands and address critical biobanking processes, including the expenses related to case collection, tissue processing, storage management, sample distribution, infrastructure, and administration (36, 37). Models that consider these aspects, such as the total life cycle cost of ownership (TLCO), facilitate a clearer understanding of the variable and fixed costs necessary for implementing cost recovery strategies (36).

Currently, there is no universally accepted method for attaining financial sustainability. However, integrating traditional funding strategies with innovative approaches to develop new sustainability and business models tailored to the unique needs of biobanks may prove essential. Enhancing societal value and public benefits while addressing the interests of stakeholders—including funders, researchers, and participants—can augment the perceived worth of biobank resources, thereby improving their long-term sustainability (34). According to Simeon-Dubach and Watson, the concept of biobanking 3.0 emphasizes that achieving economic sustainability hinges on positively influencing stakeholders' perceptions of the biobank (38). Biobanks must also confront the challenge of underutilization of biospecimens and data, which can profoundly affect their sustainability. Not all biobanks achieve success; for instance, the National Center of Tumor Diseases in Heidelberg (NCT) has successfully provided high-quality tissues for 605 research projects within a span of fewer than six years (39). Access to high-quality tissue specimens, a robust number of biobanking projects, high project completion rates, and user satisfaction are vital to the success of biobanks (39). Monitoring biobank outputs can equip stakeholders with reliable data on the biobank's value, which may facilitate increased usage, better alignment with research requirements, and mitigate risks to biobank sustainability (40). Nevertheless, obtaining quantitative data on biobank usage and contributions to research remains problematic (41), making it challenging to evaluate whether investments in biobanks yield substantial returns for scientific progress. An illustrative case is the EFS Centre-Atlantique donor's biobank, which experienced resource underutilization after ten years of sample use (42). Underutilization can stem from several factors, including poor or undocumented sample quality, ineffective governance models, restrictive policies hindering biobanks' participation in translational research, inadequate promotion of available collections, and limited patient and civil society engagement in biobank governance (43).

International Infrastructures Dedicated to Biobanks

International infrastructures in biobanking play a crucial role in facilitating collaborations among researchers, biobanks, industry stakeholders, and patients, providing essential tools, software, quality management services, as well as support concerning ethical and legal matters.

Key international infrastructures dedicated to biobanks include:

- **The International Society for Biological and Environmental Repositories (ISBER):** Founded in 1999, ISBER aims to enhance networking, promote education, and standardize biobanking practices. A primary objective is to produce guidelines that ensure high-quality specimens for future research. The "ISBER Best Practices: Recommendations for Repositories" outlines effective sample management procedures, encompassing evidence-based and consensus-based practices for specimen collection, long-term storage, retrieval, and distribution. These guidelines are routinely updated to reflect advancements in research and technology (44).
- **The European, Middle Eastern and African Society for Biopreservation and Biobanking (ESBB):** Established in 2010, ESBB focuses on enhancing biospecimen sharing through the education and encouragement of the

biobank community, fostering collaborations between biobankers and promoting cooperation between academic biobanks and industry (46).

- **The European Strategy Forum on Research Infrastructures (ESFRI):** In 2006, ESFRI identified the need for a comprehensive network of existing and newly established biobanks and biomolecular resources. This led to the proposal of the Biobanking and BioMolecular Resource Research Infrastructure (BBMRI) (47, 48). From 2008 to 2011, BBMRI received funding from the European Commission through the European Framework Programme 7 (49). In 2013, it was officially designated as a European Research Infrastructure Consortium (ERIC) (50, 51). BBMRI-ERIC is committed to providing access to quality-controlled biospecimens and associated data for cross-biobanking research, currently comprising 21 European member states, international organizations, and observers. Its role includes managing a directory of European biobanks and offering support in quality management, information technology, ethical, legal, and social implications (ELSI), as well as compliance with the General Data Protection Regulation (GDPR). BBMRI-ERIC accomplishes its objectives through active engagement with national nodes.

A Focus on Cancer-Oriented Biobanks

Cancer-oriented biobanks are specifically designed to collect and preserve human biological samples for oncological research. These biobanks primarily focus on acquiring biological specimens from patients diagnosed with cancer, alongside control samples, which consist of healthy tissues from the same cohort. They serve as a long-term repository for human biological materials, accompanied by pertinent data gathered at the time of diagnosis and throughout subsequent therapeutic phases, including pre-treatment, during therapy, at follow-ups, and in instances of disease recurrence. Given the significance of tissue samples within these biobanks, pathology laboratories play a crucial role (Fig. 1, Fig. 2). These laboratories are responsible for (i) managing specimens, (ii) evaluating and ensuring the adequacy of fresh sampling, and (iii) functioning as tissue curators accountable for the archives of formalin-fixed paraffin-embedded (FFPE) specimens. Furthermore, clinical pathology laboratories contribute to the collection of whole blood and its derivatives for routine clinical applications. This is particularly relevant as liquid biopsies are procured across various contexts, including clinical trials and translational research studies [52, 53] (Fig. 2).

Pathology laboratories may act as intermediaries between samples and biobanks or be integrated within a specific biobank. Regardless, robust collaboration with pathology laboratories is imperative to address preanalytical challenges, such as cold ischemia time and fixation duration (the latter for FFPE tissue specimens), which are vital for ensuring the integrity of tissue samples and their derivatives for molecular analyses (high-throughput). In this regard, the fixation time for FFPE samples is critical, as formalin fixation significantly influences DNA/RNA fragmentation, thus affecting the efficacy of subsequent molecular investigations. Recent studies have indicated that the temperature of formalin fixation is also a critical factor [54, 55]; employing cold fixation techniques can minimize nucleic acid degradation [54, 55, 56, 57, 58].

It is noteworthy that tissues designated for research and subsequently stored in a biobank may originate from "leftover tissues" from surgical procedures or be obtained through minor surgeries, endoscopic examinations, or ultrasound-guided biopsies. The procurement of tissue samples is always conducted in a manner that preserves the diagnostic process, which takes precedence over biobank sample collection. Conversely, any sample archived in the biobank is available for diagnostic purposes. Standard Operating Procedures (SOPs) should be clearly defined and rigorously adhered to: samples are generally collected within 15–20 minutes post-surgery and are immediately frozen, either with or without the inclusion of optimal cutting temperature (OCT) compound, to mitigate drying artifacts, prolonged exposure to ambient temperatures, cold ischemia, and mechanical artifacts resulting from the collection process. The standardization protocol incorporates quality control measures for aliquots of surgical specimens for histopathological and molecular evaluations during the fresh tissue sampling phase or when retrieving frozen and stored samples. Within pathology laboratories and biobank facilities, opportunities exist to enhance sample accessibility by aliquoting tissues embedded in OCT, conducting cryostatic sections, and providing frozen tissue sections instead of whole blocks. In certain circumstances, macro- and microdissection techniques are also employed. In summary, each stage delineated in the specimen workflow is critical for ensuring the success of precision medicine, as the quality of the sample is a fundamental prerequisite for any reliable data analysis, whether arising from single biomarker investigations or high-throughput analyses.

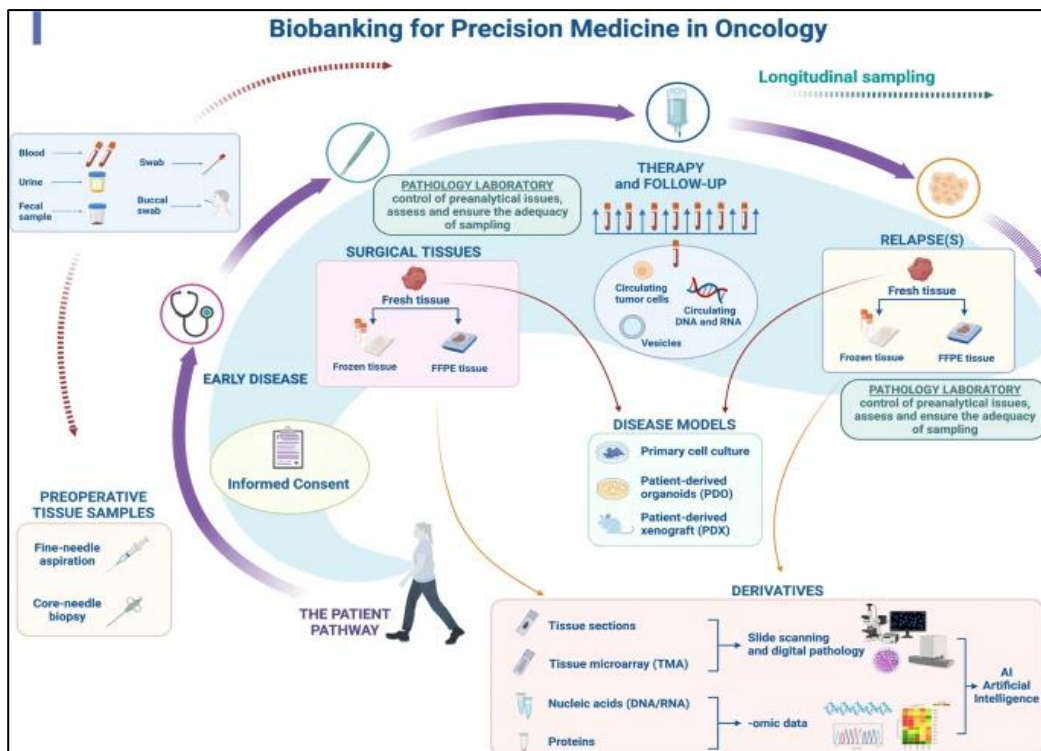


Figure 2: Biobanking plays a crucial role in advancing precision medicine within oncology

A practical example highlights how biobanking can significantly impact a patient's journey, illustrating its contributions throughout the patient's clinical history, whether in the early or advanced stages of the disease. With the patient's informed consent, various biological specimens can be collected. During the preoperative phase, samples may be obtained through techniques such as fine-needle aspiration and core-needle biopsy.

Conclusion

Biobanks play a pivotal role in modern clinical research and pathology, acting as foundational resources for advancing personalized medicine. By integrating biological samples with extensive health data, they provide researchers with the tools needed to uncover the intricate relationships between genetics, environmental factors, and disease progression. The transition from traditional biobanks, which store physical biospecimens, to virtual biobanks, which manage and analyze digitized data, signifies a transformative shift in how biological research is conducted. Virtual biobanks enhance accessibility and collaboration among researchers globally, allowing for cost-effective and efficient data sharing. This innovation not only mitigates the logistical challenges associated with physical sample transfers but also fosters collaborative research efforts that can lead to significant advancements in understanding disease mechanisms. However, as biobanks continue to evolve, they face a series of complex challenges, including ethical considerations regarding donor privacy and informed consent, as well as the need for robust governance frameworks. Furthermore, the classification systems of biobanks remain a topic of ongoing debate, as their diverse nature complicates standardization. Addressing these challenges requires a multifaceted approach, encompassing adherence to ethical guidelines, investment in infrastructure, and commitment to transparency in data management. The potential of biobanks to revolutionize health research and treatment paradigms is immense; thus, sustained efforts to navigate the intricacies of biobanking will be essential for realizing their full promise. Ultimately, as the landscape of healthcare continues to shift towards personalized approaches, biobanks will be critical in bridging the gap between basic research and clinical application, ensuring that scientific discoveries translate into meaningful health improvements for individuals and populations alike. By fostering an environment of collaboration, ethical rigor, and innovative data management practices, biobanks can continue to serve as invaluable assets in the quest for knowledge and better health outcomes.

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البنوك الحيوية ودورها في البحث السريري وعلم الأمراض

الملخص:

الخلفية: لقد اكتسبت البنوك الحيوية الاعتراف لدورها الحاسم في البحث السريري وعلم الأمراض، لا سيما في تعزيز الطب الدقيق. تمثل تطورها من البنوك الحيوية التقليدية إلى البنوك الحيوية الافتراضية تحولاً كبيراً في منهجية البحث. **biomedical**

الهدف: يتناول هذا المقال تطور وأهمية والجوانب التشغيلية للبنوك الحيوية، مع تسليط الضوء على دورها في الطب الشخصي والتحديات التي تواجهها.

الطرق: تم إجراء مراجعة شاملة للأدبيات والإرشادات المعمول بها لتحليل الخصائص والتصنيفات والحوكمة للبنوك الحيوية، مع التركيز على بنيتها التحتية وإدارة البيانات.

النتائج: تقدم البنوك الحيوية، سواء كانت مادية أو افتراضية، موارد لا تقدر بثمن لعلم الأوبئة الجزيئية والوراثية، وعلم الأمراض الجزيئية، والدوائية الجينية. تمكن الباحثين من إجراء دراسات واسعة النطاق، وتحديد المؤشرات الحيوية، وتخصيص العلاجات وفقاً للملفات الوراثية الفردية. ومع ذلك، توجد تحديات كبيرة، بما في ذلك المخاوف الأخلاقية، والتمويل، والحاجة إلى هياكل حوكمة قوية.

الخاتمة: تمثل البنوك الحيوية مكوناً حيويًا من مكونات البحث **biomedical** الحديث، مما يسهل التقدم في الطب الشخصي. بينما تقدم إمكانات هائلة، فإن معالجة التحديات المتعلقة بالبنية التحتية والأخلاقيات أمر ضروري لاستدامتها وفعاليتها في تحسين النتائج الصحية.

الكلمات المفتاحية: البنوك الحيوية، الطب الدقيق، البحث السريري، البنوك الحيوية الافتراضية، علم الأمراض الجزيئية، الاعتبارات الأخلاقية.