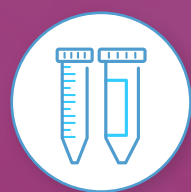


# Best Practices for Biospecimen Management

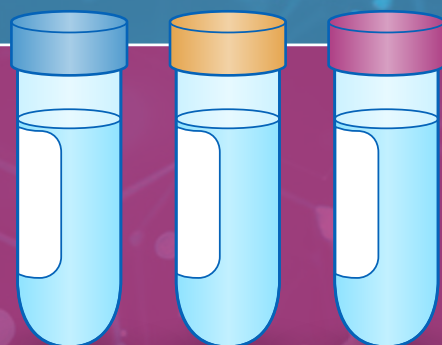
Biospecimens are the critical raw materials that fuel translational and clinical research. Proper management of these invaluable specimens is essential for generating reliable and reproducible results and also respecting patient privacy and consent agreements.

This infographic provides best practices for biospecimen management as well as offers tips on how to select a biorepository partner.



## Sample Quality

- Quality control checks should be conducted throughout all stages from collection to storage
- Personnel should be trained on proper biospecimen handling, safety protocols, and documentation requirements
- Make sure biospecimens are collected under approved protocols and with appropriate informed consent from the patient



## Data Integrity

- Biospecimens should be collected and documented by healthcare professionals (not patient reported)
- Monitoring records and compliance reports should be provided for all biospecimens



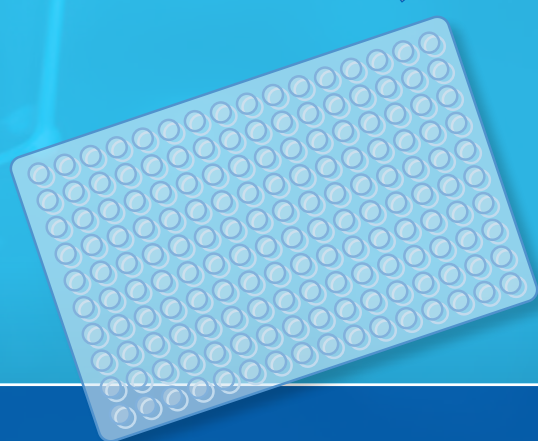
## Acquisition Planning

- Create a biospecimen plan outlining current and downstream future uses
- Ensure all intended uses are covered by consent documents



## Data Requirements

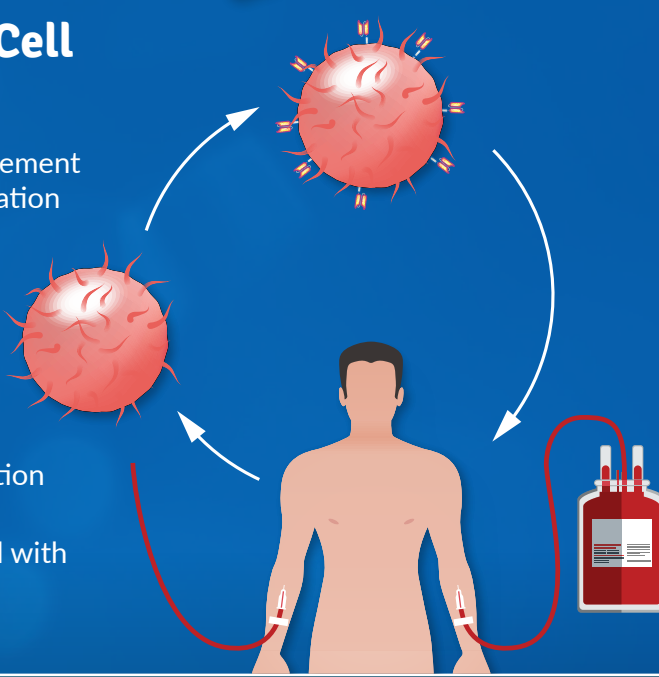
- When possible, use specimens that have been certified for multiple assays
- Request harmonized electronic data formats from sourcing partners
- Know upfront how specimens will be used (i.e., the plan) to ensure data requirements are met



## Additional Considerations for Cell Therapy Biospecimens

Cell therapies have their own biospecimen management challenges, mostly related to cold-chain transportation and *ex vivo* modification. For these therapies, additional factors need to be considered:

- Ensure all personnel understand and follow safety and regulatory requirements
- Specimen preservation should be prioritized throughout the workflow
- Rigorous cold-chain logistics and cryopreservation tracking are essential
- A long-term storage plan should be established with secure data management



## Tips on Selecting a Biorepository Partner

A biorepository's history, accreditations, quality systems, sourcing capabilities, data management expertise, and customer testimonials are all important considerations when selecting a partner. Here are some details on the key factors to consider:

- The biorepository should be: accredited by relevant organizations like AATB, HTA, CAP or CLIA; adhere to patient protection regulations like HIPAA compliance and IRB oversight; and comply with regulations like 21CFR Part 11.
- The biorepository must have the capabilities and expertise to handle the specific types of biospecimens needed for your research
- A partnership-oriented approach that prioritizes collaboration is invaluable
- Monitoring systems need to be robust, and contingency plans and back-up power sources available to maintain sample integrity
- Quality management programs should be comprehensive and include extensive QA/QC measures and rigorous documentation practices
- Extensive data management expertise is essential to ensure security of biospecimen data and also allow easy access for analysis

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