

# BioFortis

Empowering Researchers Through Innovative Software

## NEXT GENERATION BIOBANKING CHECKLIST

At the core of Next Generation Biobanking is comprehensive sample tracking and logistics, consent tracking, sample planning and a host of sample related workflows. However unlike conventional biobanking, Next Generation Biobanking is characterized by four key attributes to ensure that biospecimen management in your organization is ready for the demands of both current and future biomarker-led development and research.

### ENHANCED SECURITY AND COMPLIANCE

- Fine-grained access and security controls that extend to all data linked to a biospecimen, to ensure compliance with patient consent and regulatory guidelines.

### SUPPORT FOR EXTERNALIZED COLLABORATIVE STUDIES

- Providing the critical information infrastructure to leverage a distributed research ecosystem and its network of collaborators, partners and vendors.

### HARMONIZATION OF BIOSPECIMENS WITH CLINICAL AND MOLECULAR INFORMATION

- This requires tight linkage of the biospecimen with the plethora of molecular and clinical data collected during the course of a study or clinical trial.

### GENERATION OF SCIENTIFIC INSIGHTS

- Requires powerful tools in the hands of the researcher to facilitate data exploration and hypotheses driven research without programming or IT support.

## NEXT GENERATION BIOBANKING CHECKLIST

The checklist has been created in order to help you bring your biobank into the Next Generation. Based on the four attributes above the checklist identifies the key items to be aware of and provides a way for you to rate their importance for your organization.

**1. Operational biobanking** workflows to track biospecimens and logistics, such as receipt, request, dispensation, retention, destruction, request for analysis, sample planning and inventory reconciliation.

*At the core of next generation biobanking is the need to handle millions of specimens across the "virtual biobank" of multiple partners and vendors.*

### IMPORTANCE

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**2. Core support** for study subjects/patients, studies linked to biospecimens and their associated clinical and molecular data.

*Most traditional biobanking systems are sample centric, to maximize the value of biomarker based data, it is key that the biospecimens can be linked to subject data. The ability to support study workflows is also very important for those companies gathering samples from clinical studies to drive future research.*

### IMPORTANCE

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**3. Comprehensive tracking** of consent for specimens both in-life and future use. Consent reconciliation, verification and validation.

*The ramifications from a regulatory perspective of inconsistencies in consent records could severely impact a trial or future project.*

### IMPORTANCE

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**4. Ability to** easily and fully annotate specimens with rich clinical, molecular, specimen assay and patient data.

*Many organizations see the next generation biobank as a knowledge base of biomarker data. Rich annotations lie at the heart of that expectation.*

### IMPORTANCE

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**5. Support for** integration with multiple disparate data sources, e.g. EMR, ELN, CTMS, EDC and in house systems to support comprehensive annotation.

*The collection and harmonization of multiple data sources linked to biospecimens allows rich phenotypes to be built – increasing the value of biospecimen assets and enabling scientific insights.*

### IMPORTANCE

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**6. Ability to** configure and track samples in storage both physical and "virtual" while retaining and reporting on custodial information.

*The next generation biobank has to operate in a complex ecosystem of stakeholders where samples may never be physically stored locally. The ability to create a unified view of samples and their data as a virtual bank is therefore necessary.*

### IMPORTANCE

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**7. Capability to** create and register Studies and assign samples and patients to studies based on IRB protocols.

*The next generation biobank natively supports studies, enrolls patients to them and tracks consent for sample usage and analysis both in-life of the study and for future use.*

**IMPORTANCE**

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**8. Native support** for Protected Health Information (PHI) security according to regulatory rules and local/international agencies.

*The next generation biobank must handle PHI to ensure that the full value of the information is utilized while maintaining regulatory compliance.*

**IMPORTANCE**

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**9. Secure, easy** access from multiple locations by different user types, e.g. CRO, vendor, academic collaborator.

*The next generation biobank supports the distributed research ecosystem.*

**IMPORTANCE**

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**10. Highly flexible** and fine-grained access controls to define what users can see and do.

*Since biomarker research is very multidisciplinary there are a wide variety of users across a wide variety of organizations that may need to access the system.*

**IMPORTANCE**

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**11. Forecast anticipated** biospecimen storage needs based on the study protocol and other data.

*Vital to efficient study execution, the next generation biobank should aid users to ensure sample storage is managed and planned effectively. The ability to create a study in its entirety and forecast storage and sample receipt timelines and then reconcile actual vs. anticipated is valuable functionality, not often found in traditional biobanks.*

**IMPORTANCE**

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**12. Flexible management/reporting** of sample retention criteria, such as sample age, volumes, quality, storage conditions, consent.

*A real-time unified view on all the biobank assets is important to respond to sample request for analyses or research programs.*

**IMPORTANCE**

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**13. Ability to** create specific workflows and user interfaces for different user types, e.g. operator, CRO, clinical ops specialist.

*Helps to reduce errors, drive compliance and reduce training needs in performing day-to-day operations.*

**IMPORTANCE**

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**14. Comprehensive reporting** and dashboards.

*With real-time information, the next generation biobank is able to aid decision making and deliver actionable outcomes.*

**IMPORTANCE**

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**15. Ability for** users and domain experts to explore and ask questions of the richly annotated biospecimen data without IT involvement, or programming.

*The next generation biobank is expected to be a source of knowledge for biomarker-based discovery and generate scientific insights. The ability to quickly ask sophisticated questions of the data is key to generating these insights. Next generation biobanking provides tools so that domain experts can collaborate to ask these questions.*

**IMPORTANCE**

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# Bring Your Biobank To The **NEXT GENERATION** with **BIOFORTIS SOFTWARE**

See how BioFortis' Next Generation Biobanking software platform can help your organization meet the demands of biomarker-based research.

your completed biobanking checklist and schedule a free, no obligation consultation with one of our application scientists.



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