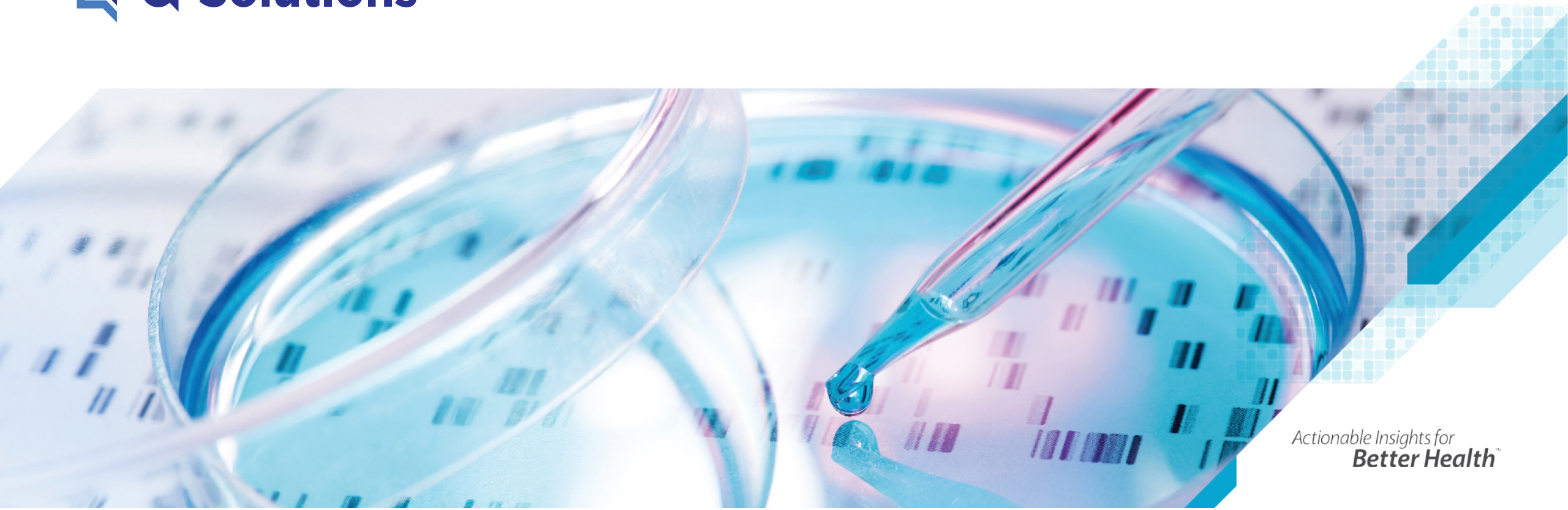
Q² Solutions®



eConsent and BioBanking
How to Reduce Costs While Improving Efficiencies

April 2019

Agenda

- What is eConsent, and how do I optimize its use?
- What is BioFortis and how does it fit with eConsent and Biobanking?
- Where does eConsent intersect with Biobanking?
- What are some of the basic principles to successfully integrate eConsent with management and use of Biobanked samples?
- What are the benefits of an integrated approach to eConsent and Biobanking?

Your Presenters

Driving Transformation in Your Clinical Trial Site Payment Process

Eric Delente, President, Patient Consent, DrugDev (an IQVIA company)

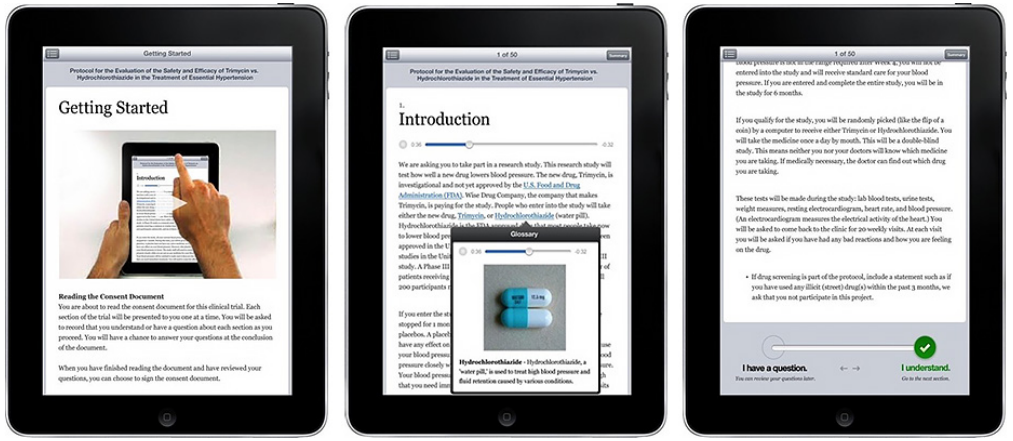
Eric has been designing, developing, hosting and maintaining award-winning, small and large-scale education portals for healthcare and science organizations for more than 20 years. As the President of the Patient Solutions business unit of DrugDev, Eric's focus is on DrugDev's leading eConsent product that provides a comprehensive electronic informed consent platform and services for clinical trials, registries, biobanking and hospital procedures to a rapidly growing network of Pharmaceutical companies and healthcare providers.

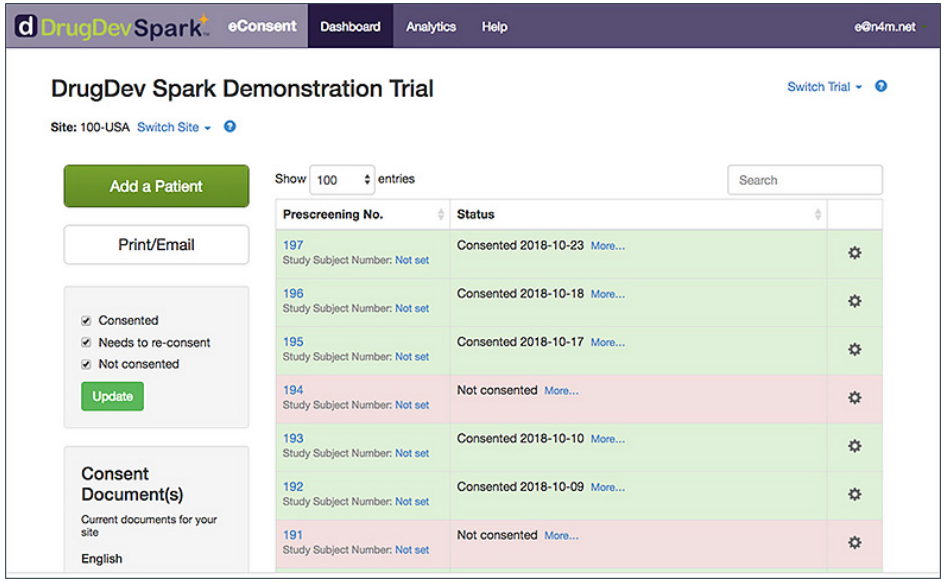
Dr. Jian Wang, Chief Executive Officer, BioFortis (a Q^2 Solutions company)

Dr. Wang is the CEO of BioFortis, the precision medicine and technology solutions offering, a Q^2 Solutions and IQVIA company. For more than 20 years, Dr. Wang developed several software products with pharmaceutical customers, government agencies, and academia. He has deep knowledge in the rapidly evolving field of precision medicine and its associated biomarker-driven clinical trials, and strives to bring precision medicine technology solutions to researchers to help solve real-world health problems.

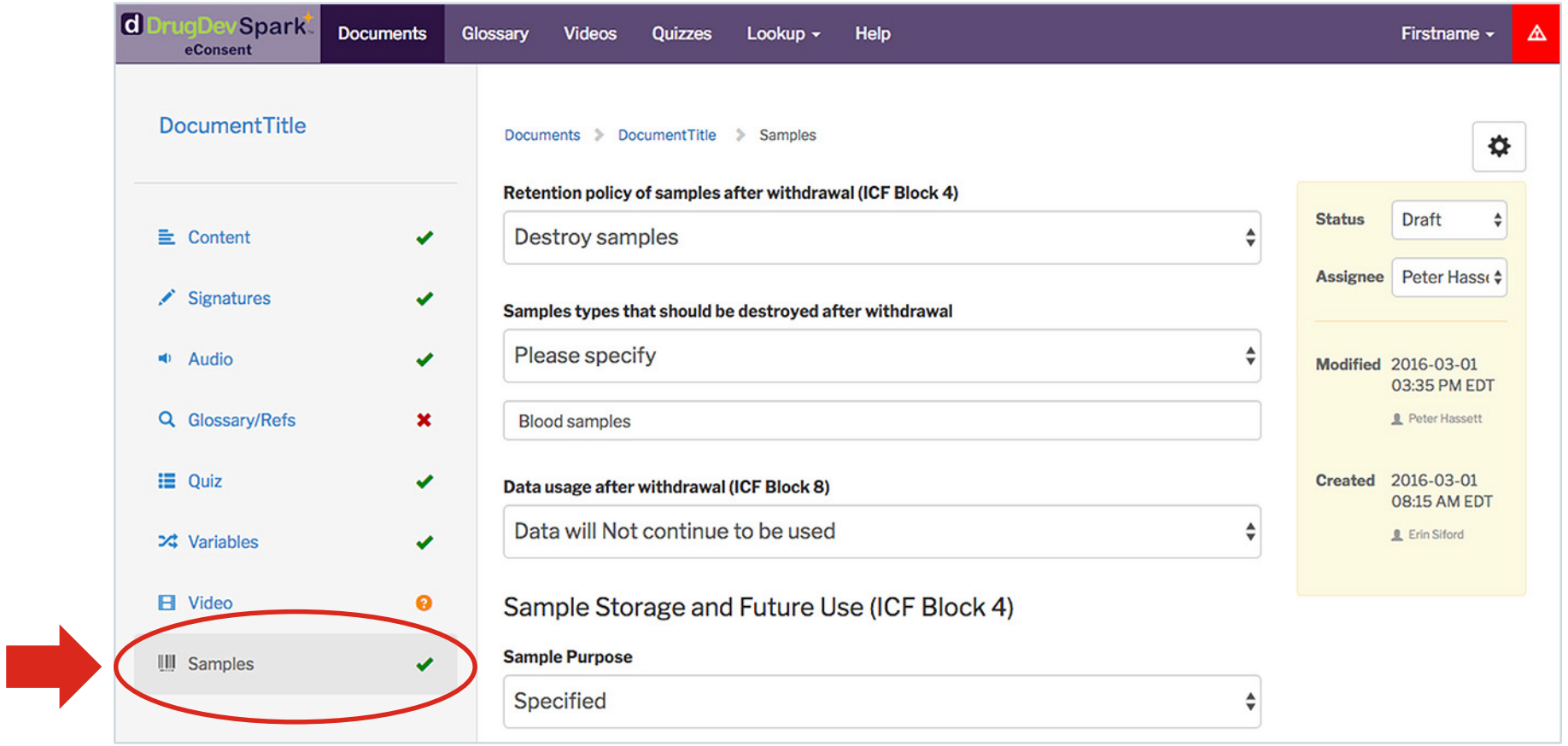
What is eConsent?

- An engaging multi-media approach towards informed consent that uses a combination of technology, graphics, audio, and video to educate and consent patients to clinical trials
- eConsent improves patient comprehension of what their study participation will involve
- eConsent reduces the potential for common consent-related audit findings and deviations through a robust audit trail
- eConsent can be integrated with other ‘eSystems’, which can reduce manual consent-related data entry and improve data quality
- *Patients who agree to submit biobank samples must consent to do so…*





Biosample attributes



Biosample attributes can now become properties of an IC document.
While entering ICF content, admin can also specify its biosample attributes.

Biosample attributes of ICFs

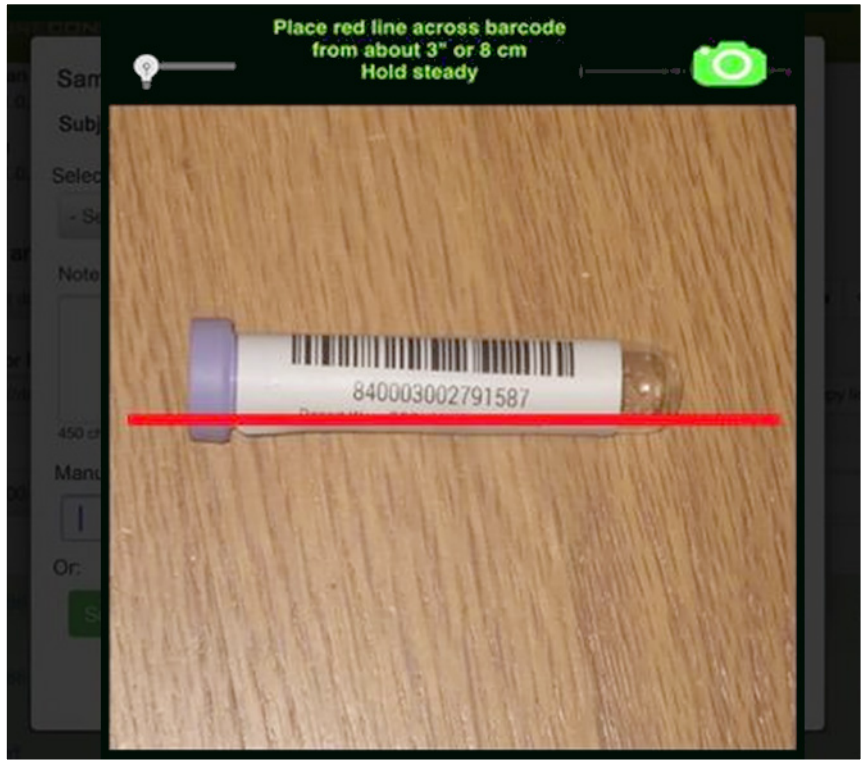
Attributes can change with each version/amendment of the ICF

If there are multiple ICFs, each can contain its own attributes

Attributes are queryable: *find all documents/sites/studies where future use research is not limited.*

Biosample attributes per document can be exported in CSV.

Look up attributes using a sample



1. After subject consents and has sample taken, associate sample with subject by scanning the code.
2. Later, scan the sample again into the consent system using code reader
3. System returns up-to-date biosample attributes for the subject belonging to the sample

Learn the current disposition of any sample instantly ...without going back to patient's identity and full-text of their signed ICFs.

Biosample Tracking - Brief Case Study

- Top-20 Sponsor collected over 1.2M samples over the last 8 years
- Following an audit, it was determined that they were unable to adequately determine what patients actually consented to for 600,000 of these samples.

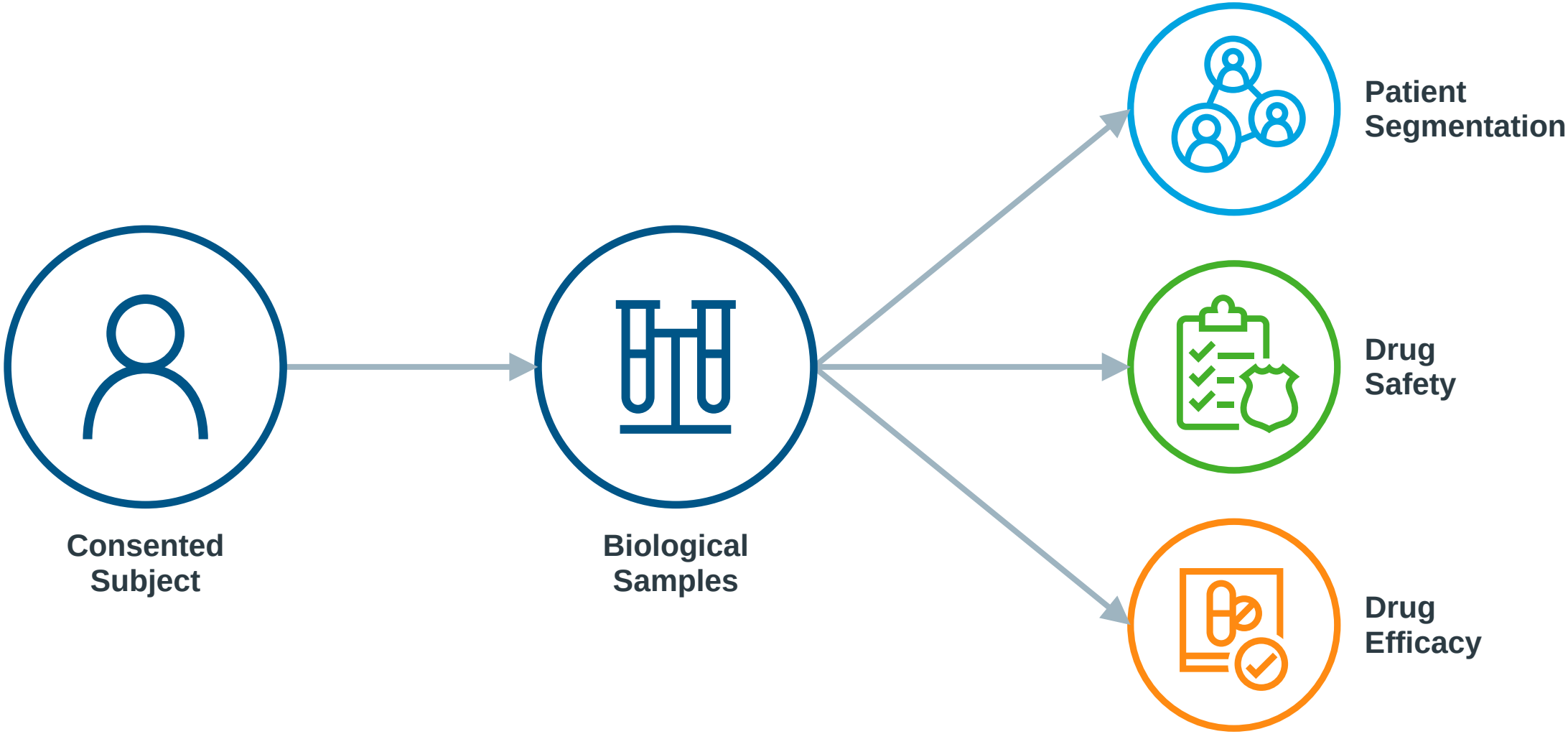
Biosample Tracking - Brief Case Study

The causes for this issue were mostly related to inadequate/incorrect manual annotation of each consent form into a massive, error-prone spreadsheet tracker.

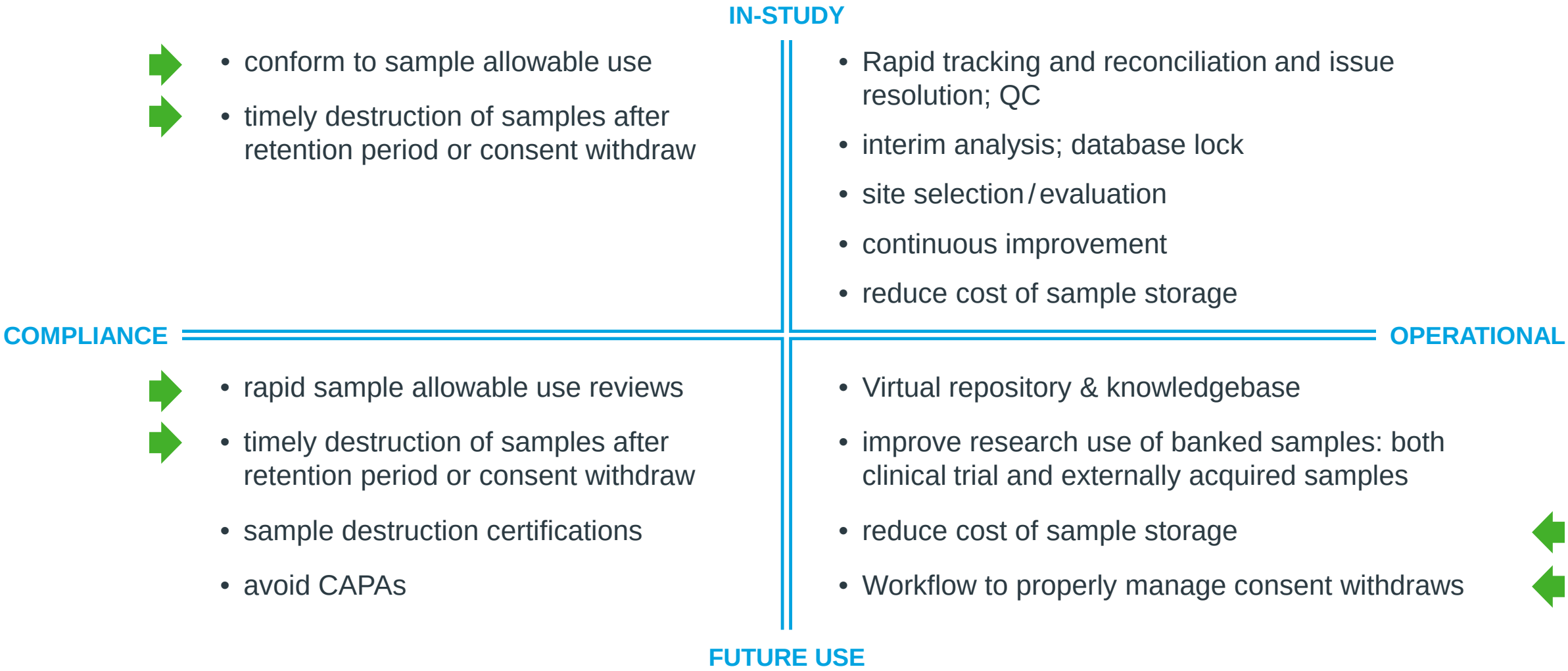
*This sponsor determined that the 'street' value of a sample that is fit-for-purpose is about **$5,000**.*
($5000 X 600,000 = $3,000,000,000)

*It takes at least **15** minutes to enter this data – after the ICFs are pulled from TMF, or about **150,000** hours for **600,000** samples…*

Consent → Subject → Sample → Data → Drug



Value of Properly Tracking Samples and Consents

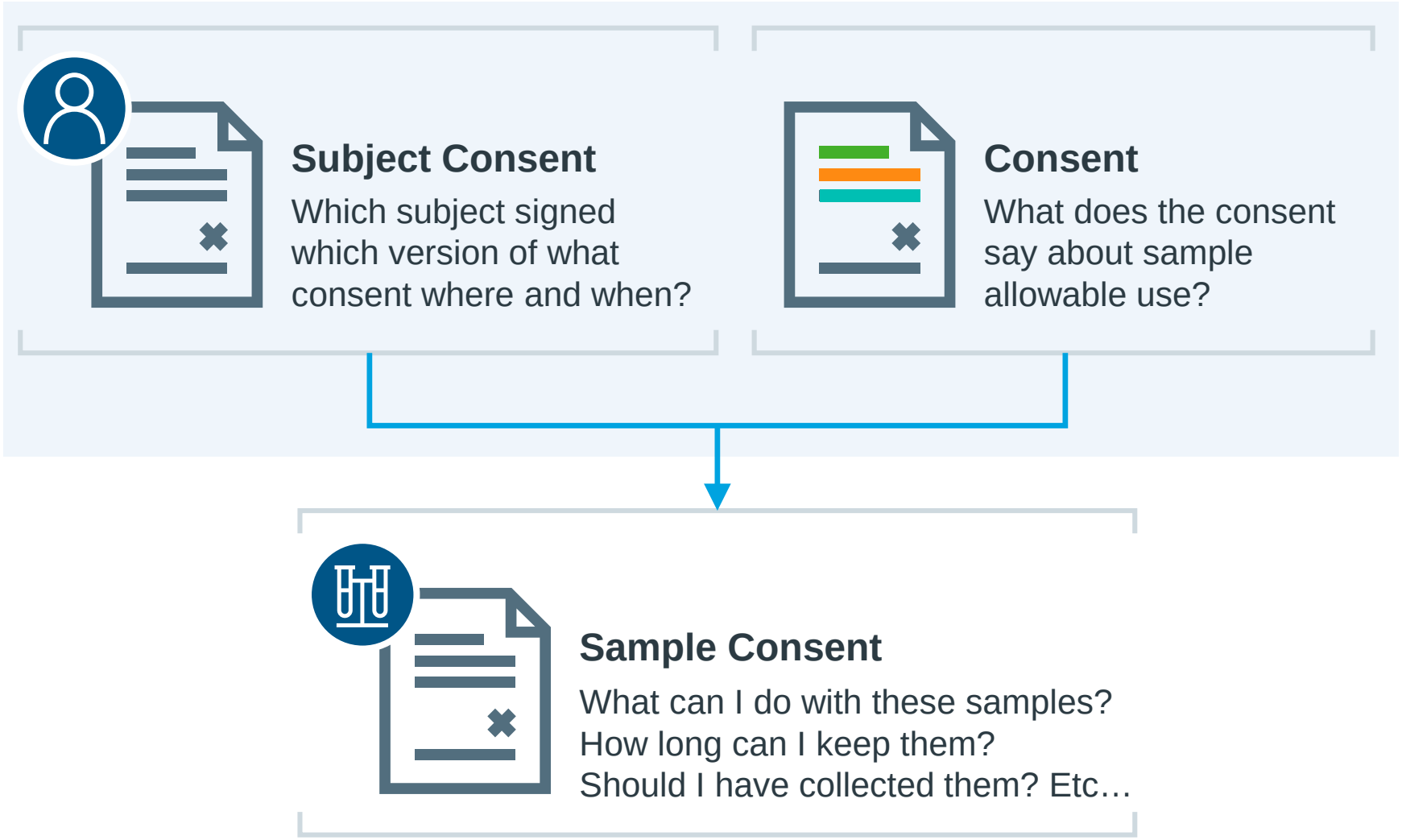


How to leverage your clinical specimen assets?

Is not about # samples you store

Is about # samples you effectively use
…or destroy

eConsent Integration



Consent - Key Concepts

CONSENT

Consent - Key Concepts

Hierarchical Consent Example

Consent Configuration:

Level	Consent Type	Country	Site	Storage Duration	Genetic Study
Study	Main			15	Yes
Country		United Kingdom		10	
Site	Main	United Kingdom	100	5	No
	Main	United Kingdom	101		No
	Main	United Kingdom	102	5	

In Effect:

- Site 100: 5 year storage; No genetic study
- Site 101: 10 year storage; No genetic study
- Site 102: 5 year storage; Yes genetic study
- Site 103: 15 year storage; Yes genetic study

Consent Versioning Example in Labmatrix

Consent Configuration:

Site	Consent Type	Start Date	End Date	Storage Duration	Genetic Study
100	Main	1/1/2015	12/31/2015	10	No
100	Main	1/1/2016		11	Yes
101	Main	3/1/2015		12	Yes

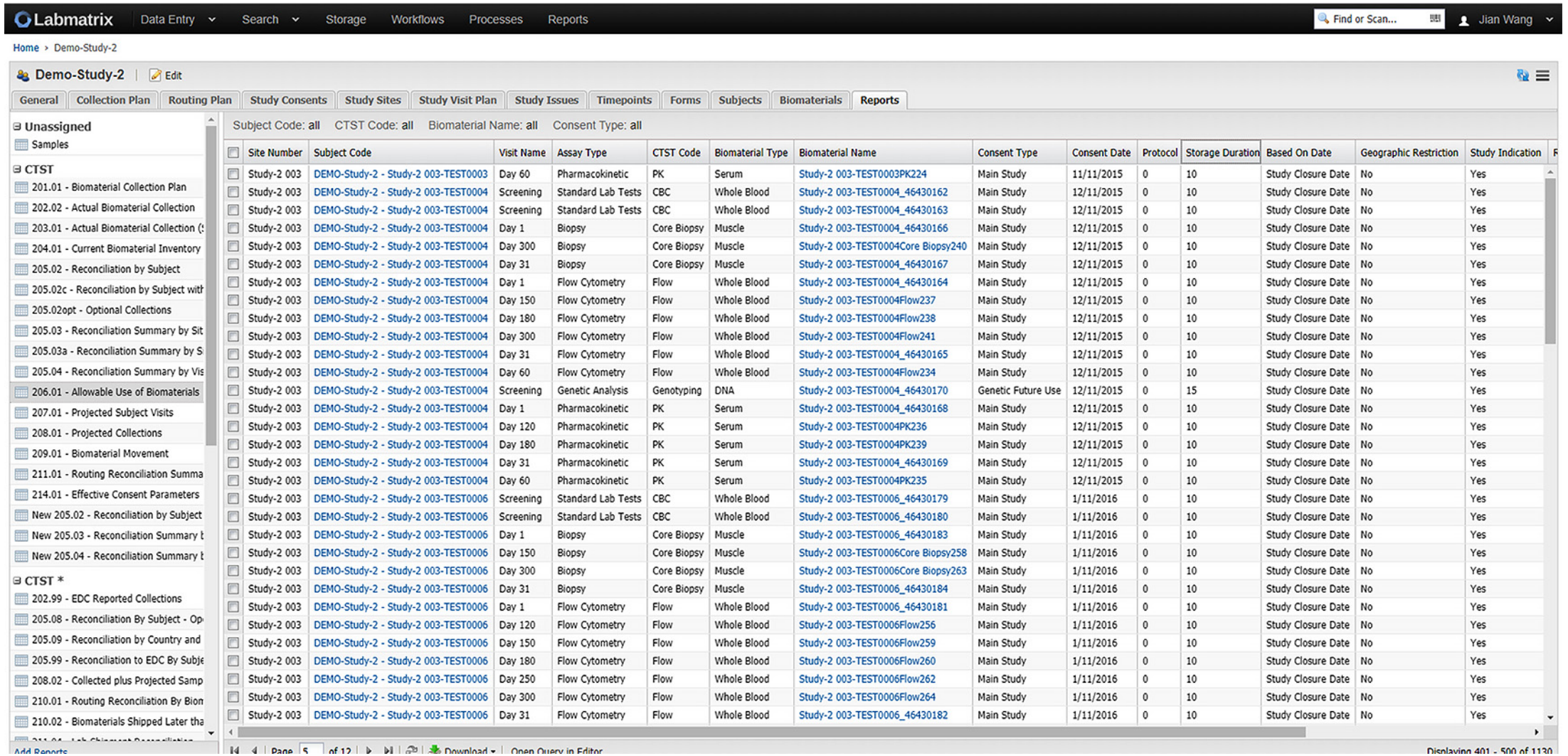
Subject Consent:

Site	Subject	Consent Date	Consent Type	Withdrawn
100	100-001	5/5/2015	Main	No
100	100-002	3/5/2016	Main	No
101	101-001	6/1/2015	Main	No

In Effect:

Site	Subject	Consent Date	Consent Type	Storage Duration	Genetic Study
100	100-001	5/5/2015	Main	10	No
100	100-002	3/5/2016	Main	11	Yes
101	101-001	6/1/2015	Main	12	Yes

Finally…


Labmatrix
Data Entry
Search
Storage
Workflows
Processes
Reports
Find or Scan...
Jian Wang
Home › Demo-Study-2
Demo-Study-2 | Edit
General
Collection Plan
Routing Plan
Study Consents
Study Sites
Study Visit Plan
Study Issues
Timepoints
Forms
Subjects
Biomaterials
Reports
Unassigned
Samples
CTST
201.01 - Biomaterial Collection Plan
202.02 - Actual Biomaterial Collection
203.01 - Actual Biomaterial Collection (
204.01 - Current Biomaterial Inventory
205.02 - Reconciliation by Subject
205.02c - Reconciliation by Subject with
205.02opt - Optional Collections
205.03 - Reconciliation Summary by Sit
205.03a - Reconciliation Summary by S
205.04 - Reconciliation Summary by Vis
206.01 - Allowable Use of Biomaterials
207.01 - Projected Subject Visits
208.01 - Projected Collections
209.01 - Biomaterial Movement
211.01 - Routing Reconciliation Summa
214.01 - Effective Consent Parameters
New 205.02 - Reconciliation by Subject
New 205.03 - Reconciliation Summary b
New 205.04 - Reconciliation Summary b
CTST *
202.99 - EDC Reported Collections
205.08 - Reconciliation By Subject - Op
205.09 - Reconciliation by Country and
205.99 - Reconciliation to EDC By Subje
208.02 - Collected plus Projected Samp
210.01 - Routing Reconciliation By Bion
210.02 - Biomaterials Shipped Later tha
Add Reports
Subject Code: all CTST Code: all Biomaterial Name: all Consent Type: all
Site Number | Subject Code | Visit Name | Assay Type | CTST Code | Biomaterial Type | Biomaterial Name | Consent Type | Consent Date | Protocol | Storage Duration | Based On Date | Geographic Restriction | Study Indication
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0003 | Day 60 | Pharmacokinetic | PK | Serum | Study-2 003-TEST0003PK224 | Main Study | 11/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Screening | Standard Lab Tests | CBC | Whole Blood | Study-2 003-TEST0004_46430162 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Screening | Standard Lab Tests | CBC | Whole Blood | Study-2 003-TEST0004_46430163 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 1 | Biopsy | Core Biopsy | Muscle | Study-2 003-TEST0004_46430166 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 300 | Biopsy | Core Biopsy | Muscle | Study-2 003-TEST0004Core Biopsy240 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 31 | Biopsy | Core Biopsy | Muscle | Study-2 003-TEST0004_46430167 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 1 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0004_46430164 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 150 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0004Flow237 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 180 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0004Flow238 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 300 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0004Flow241 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 31 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0004_46430165 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 60 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0004Flow234 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Screening | Genetic Analysis | Genotyping | DNA | Study-2 003-TEST0004_46430170 | Genetic Future Use | 12/11/2015 | 0 | 15 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 1 | Pharmacokinetic | PK | Serum | Study-2 003-TEST0004_46430168 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 120 | Pharmacokinetic | PK | Serum | Study-2 003-TEST0004PK236 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 180 | Pharmacokinetic | PK | Serum | Study-2 003-TEST0004PK239 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 31 | Pharmacokinetic | PK | Serum | Study-2 003-TEST0004_46430169 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0004 | Day 60 | Pharmacokinetic | PK | Serum | Study-2 003-TEST0004PK235 | Main Study | 12/11/2015 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Screening | Standard Lab Tests | CBC | Whole Blood | Study-2 003-TEST0006_46430179 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Screening | Standard Lab Tests | CBC | Whole Blood | Study-2 003-TEST0006_46430180 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 1 | Biopsy | Core Biopsy | Muscle | Study-2 003-TEST0006_46430183 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 150 | Biopsy | Core Biopsy | Muscle | Study-2 003-TEST0006Core Biopsy258 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 300 | Biopsy | Core Biopsy | Muscle | Study-2 003-TEST0006Core Biopsy263 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 31 | Biopsy | Core Biopsy | Muscle | Study-2 003-TEST0006_46430184 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 1 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0006_46430181 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 120 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0006Flow256 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 150 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0006Flow259 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 180 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0006Flow260 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 250 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0006Flow262 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 300 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0006Flow264 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Study-2 003 | DEMO-Study-2 - Study-2 003-TEST0006 | Day 31 | Flow Cytometry | Flow | Whole Blood | Study-2 003-TEST0006_46430182 | Main Study | 1/11/2016 | 0 | 10 | Study Closure Date | No | Yes
Page 5 of 12
Download
Open Query in Editor
Displaying 401 - 500 of 1130

Benefits

Reduction in Risk

Improvements to monitoring and management of consents will reduce the company's exposure to potential compliance risk in the use of samples for exploratory purposes. Furthermore, a near real-time holistic view will reduce the time to respond to regulatory questions.

Reduction in Costs

Consolidating sample, patient and trial information will improve the usage of samples. Exploratory samples were underutilized, because of consent issues and because a holistic view of sample information is not available. Improving sample usage will reduce additional sample procurements, resulting in significant savings (25%-35%) to the current annual multimillion dollar sample procurement budget. Increased operational efficiency (due to fewer sample issues) also improves timeline and reduces cost.

Integrating eConsent and Consent Lifecycle Management

- Joint Offering: automated codification (parameter generation) from eConsent platform to Labmatrix
- The eConsent data is transferred to the Labmatrix biobank management system
- Consent Variables are associated with samples and stored in the Labmatrix database for each study, subject, and sample
- Automated alerts for storage deadline adherence
- Alerts and reports provided via portal
- Consent withdrawals entered; sample destruction notification included

Labmatrix

Thank You

- Eric Delente
- President, Patient Consent, DrugDev (an IQVIA company)
- Eric.Delente@DrugDev.com

- Dr. Jian Wang
- Chief Executive Officer, BioFortis (an IQVIA company)
- jwang@biofortis.com