TRANSLATIONAL RESEARCH INFORMATION PLATFORM

Bio-IT World Conference and Expo

APRIL 5, 2016

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AMGEN R&D IT

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ConvergeHEALTH BY DELOITTE

AMGEN®

Pioneering science delivers vital medicines™

OUTLINE

1. **Introductions**
2. **Emerging Trends in Evidence Lifecycle Management**
3. **Implications for Translational Research**
4. **Amgen Translational Research Information Platform (TRIP)**
   - Background
   - TRIP Vision and Business Outcomes
   - Logical Data Tiers
   - Target Architecture
   - Example Use Cases and Screen Shots
   - Upcoming Plan for 2016 - 2017

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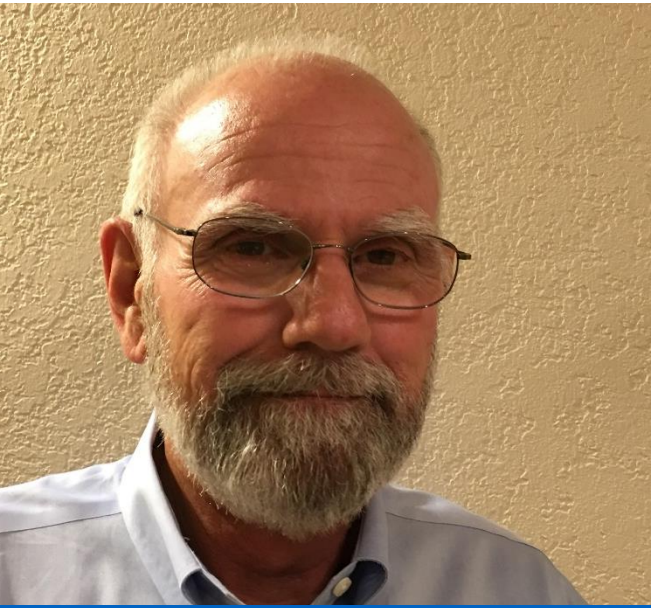
INTRODUCTIONS



George Seegan

Dr. Seegan is a member of the Research and Development Informatics group at Amgen and leads Information Technology support for the Translational Sciences area. He is a veteran research and development IT leader in the biotech and pharma space with many years' experience implementing computational and informatics platforms for drug discovery and clinical development applications. He has broad experience implementing technical software development solutions to support laboratory information management, scientific and clinical data analysis, and high-performance computing to support modeling and simulation. His experience includes extensive development and validation of computer systems used in regulated environments and managing the operational, quality, and compliance issues surrounding them. Prior to joining Amgen in 2002, George served as Vice-President Information Technology at Esoterix—Endocrine Sciences. George received his BS in Chemistry and Ph.D. in Biochemistry from UCLA.

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INTRODUCTIONS

David Hardison

Dr. Hardison focuses on helping clients integrate evidence planning and generation throughout the product life cycle and value dossier development process. This includes strategies and tactics for gaining optimal insights from both proprietary data and Real World Data to help clients improve the benefit-risk profiles of their products. David also has extensive experience aligning R&D IT strategy with R&D business strategy for biopharmaceutical companies, government health and research organizations, and healthcare providers in the areas of Global R&D Operations, Data Transparency and Standards, Submission Management, Pharmacovigilance, Translational Research, and Big Data. Additionally, he has served as a strategic advisor to healthcare executive teams, physician organizations and boards of trustees on continuous quality improvement and served as the CIO of a large health system. David's PhD in Biostatistics, undergraduate degrees in Computer Science and Math, and expertise across the healthcare ecosystem, qualify him as a Data Scientist by any definition. David has served in several industry leadership roles and is currently Chairman of the CDISC Board of Directors.

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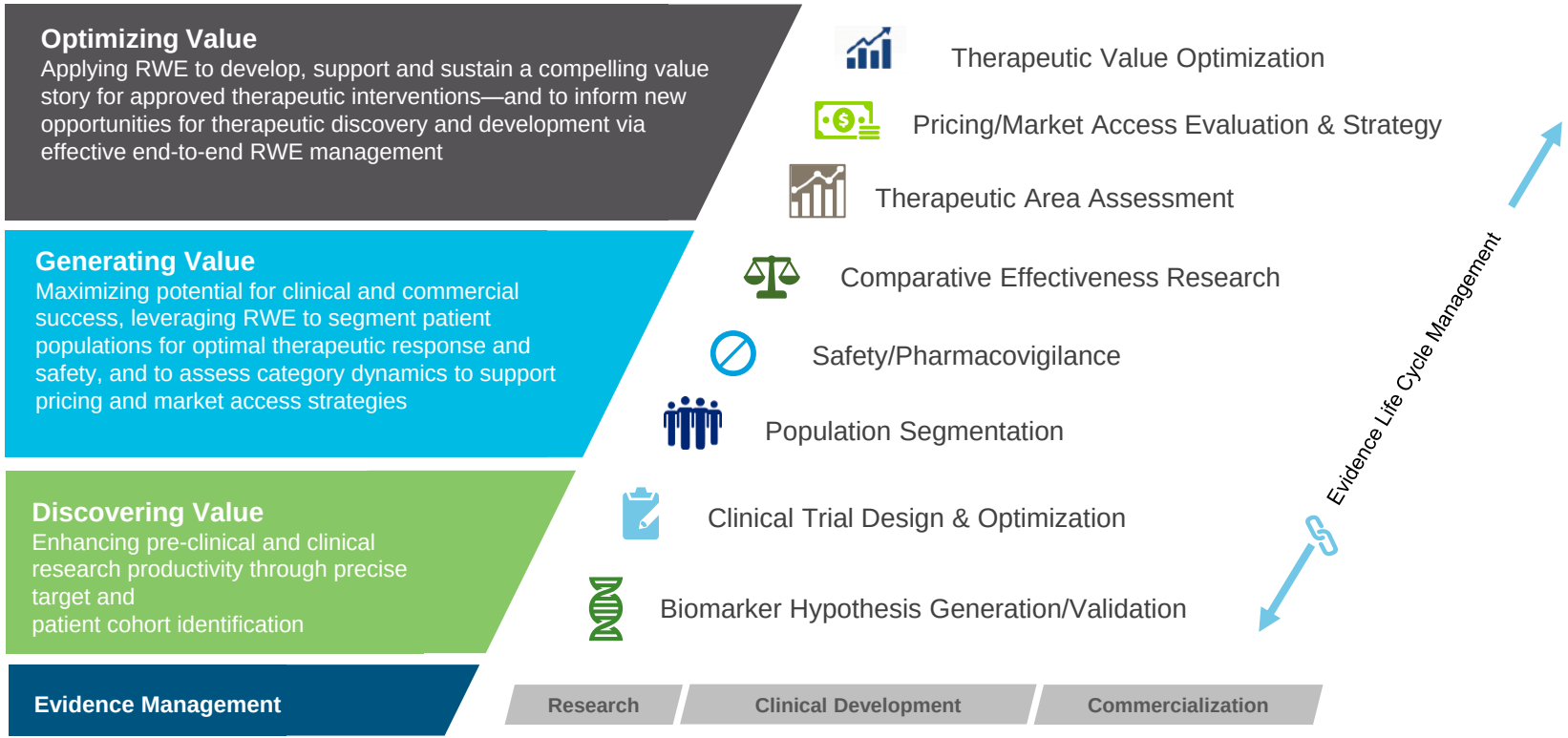
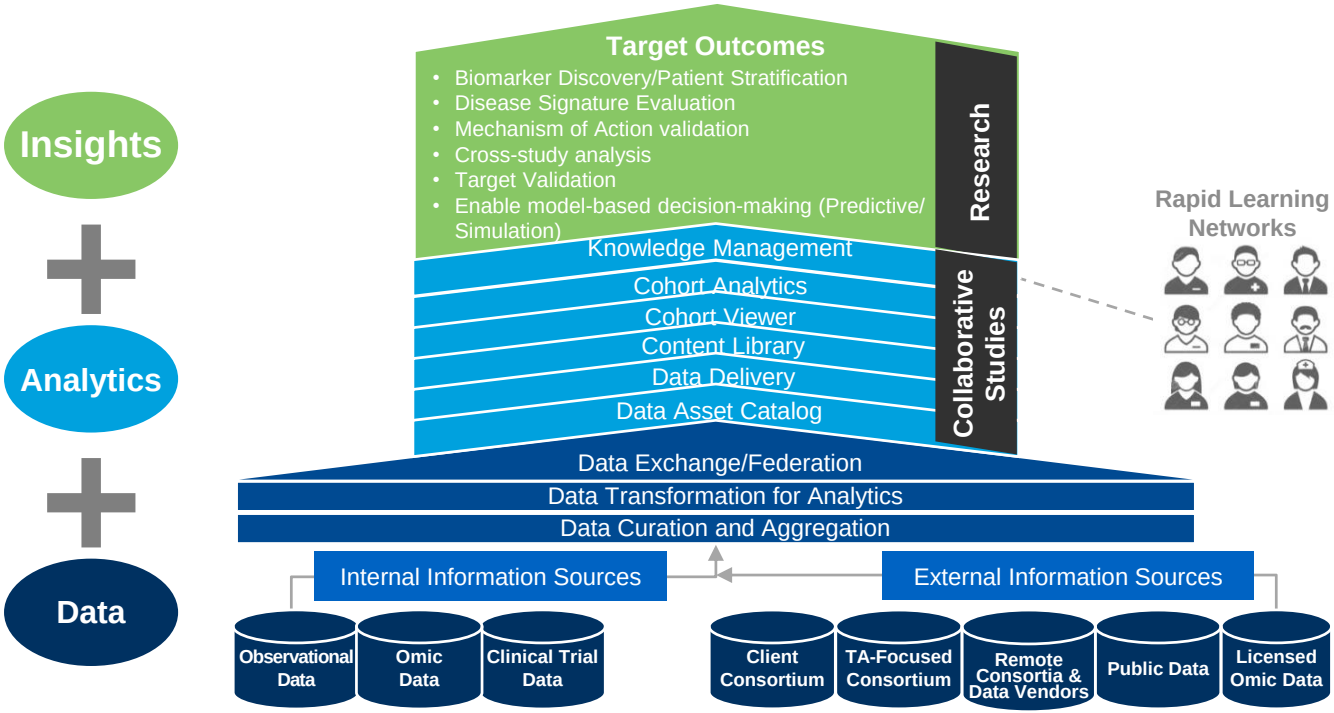
EMERGING TRENDS IN EVIDENCE LIFECYCLE MANAGEMENT



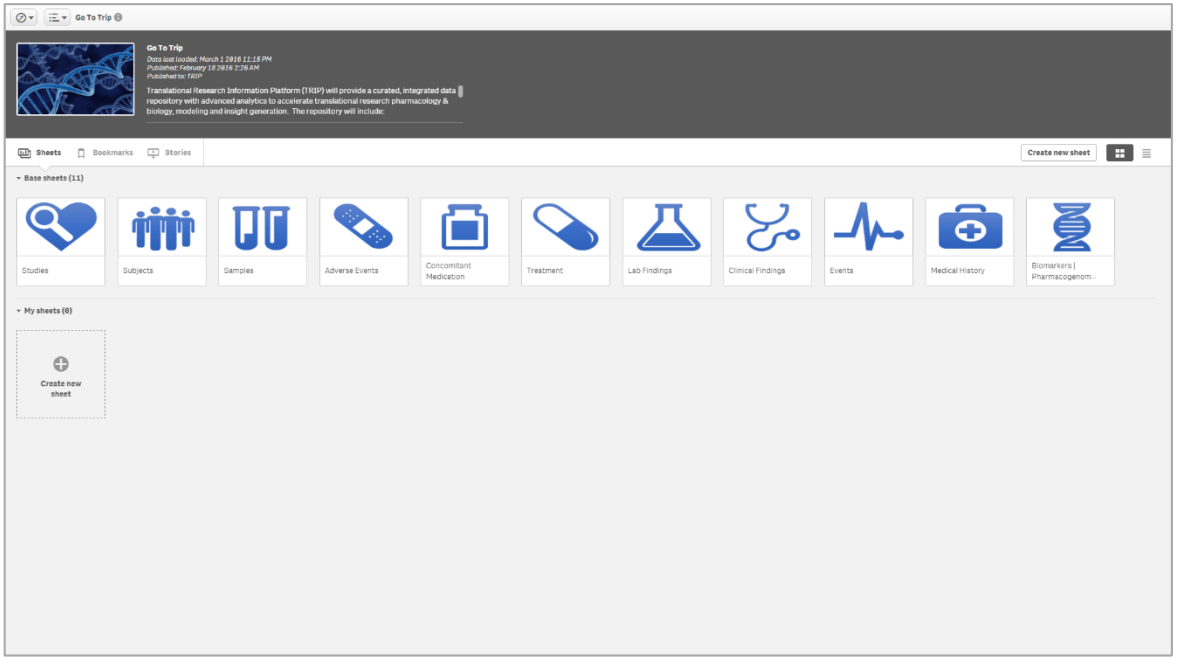
IMPLICATIONS FOR TRANSLATIONAL RESEARCH

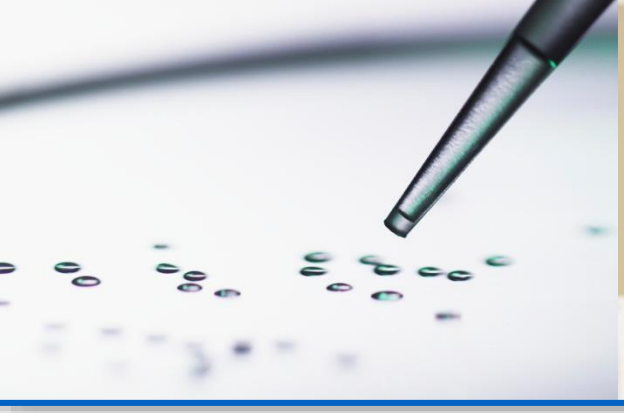
A suite of applications built on common data platforms tightly integrated to enhance collaboration is essential



AMGEN TRANSLATIONAL RESEARCH INFORMATION PLATFORM

TRIP will be a cloud-based, information integration factory that delivers relevant data on demand to researchers through an easy to use, extensible analytics and visualization portal.





EPOGEN® (EPOETIN ALFA) RECOMBINANT

NEUPOGEN® (FILGRASTIM)

Aranesp® (darbepoetin alfa)

Neulasta® (pegfilgrastim)

Enbrel® etanercept

Sensipar® (cinacalcet) Tablets 30mg · 60mg · 90mg

FIRST-IN-CLASS Mimpara® cinacalcet

Vectibix® (panitumumab) Injection for IV Infusion

Nplate® romiplostim

prolia® (denosumab) injection

XGEVA® (denosumab)

Nexavar® (sorafenib) tablets

Kyprolis™ (carfilzomib) for injection

BLINCYTO® (blinatumomab) for injection 35 mcg single-use vial

Corlanor® (ivabradine) 5 mg 7.5 mg tablets

Repatha™ (evolocumab) injection 140 mg/mL

IMLYGIC™ (talimogene laherparepvec) SUSPENSION FOR INJECTION 10^6 PFU/mL and 10^8 PFU/mL single-use vials

For additional information about Amgen products, including important safety information, please visit amgen.com; NEXAVAR® (sorafenib) is developed and marketed under collaboration and co-promotion agreements with Bayer HealthCare

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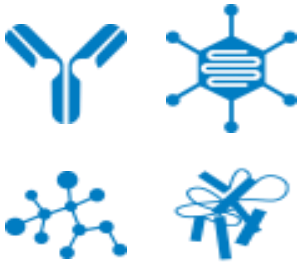
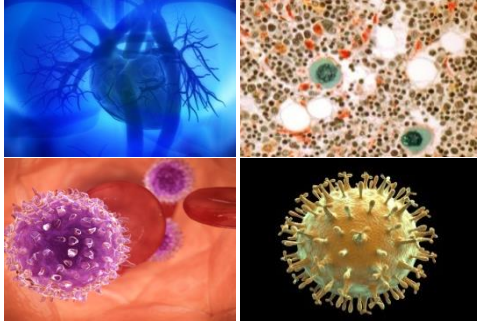
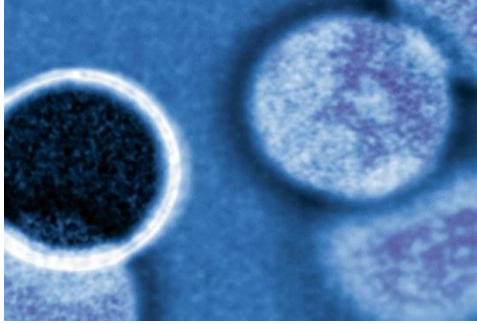
Genetic Validation



Biology First Advantage



Investing In Innovation



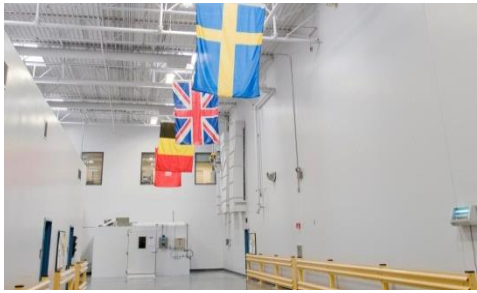
Protein Engineering

Global Clinical Trials

Biologics Manufacturing

Repatha® (evolocumab) injection 140 mg/mL

Successful Launch Track Record



Global Commercial Infrastructure

Fully Integrated Biotechnology Company

World-class capabilities

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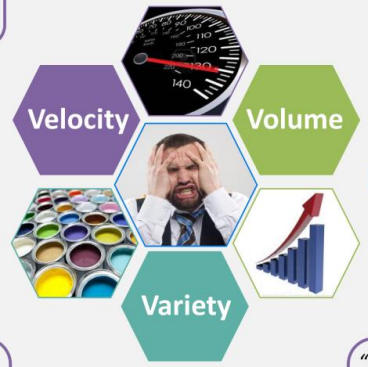
TRANSLATIONAL RESEARCH PROBLEM STATEMENT

Don't We Have Those Data Somewhere?

"How often did this adverse event show up in the placebo arm for this program?"

"What exactly was measured in the TREAT study? What other study was that measured in?"

Where are the data?



Do data exist?

How to obtain data?

How to integrate data?

"We had non-responders in several clinical studies for AMG 000 – what were the lab tests for those subjects?"

"Can we get blood samples from patients in oncology studies before and after drug treatment? I only want the ones with high lab values"

ROUGH ROAD

Data are disconnected in silos, concealing key insights that could be gained through integrated data mining across programs and projects

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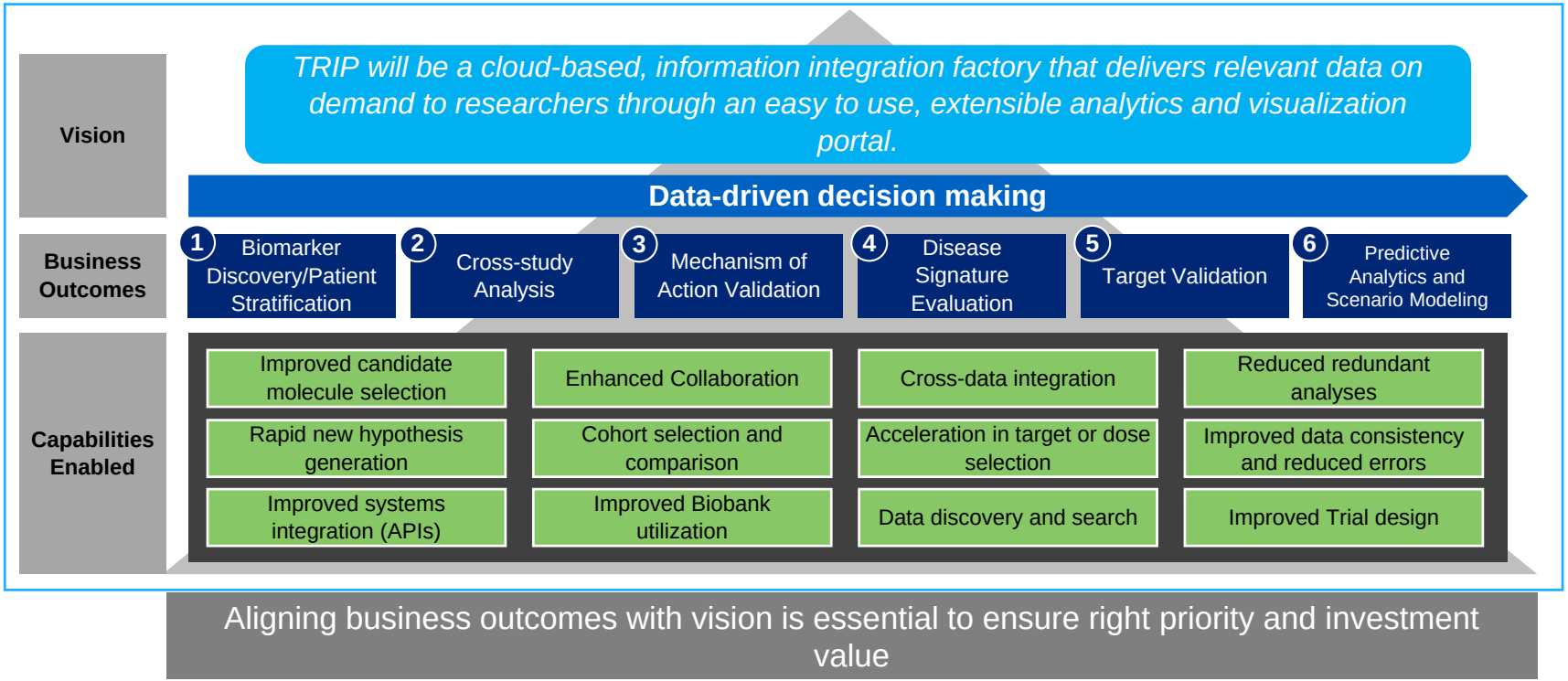
VISION AND KEY BUSINESS OUTCOMES



Aligning business outcomes with vision is essential to ensure right priority and investment value

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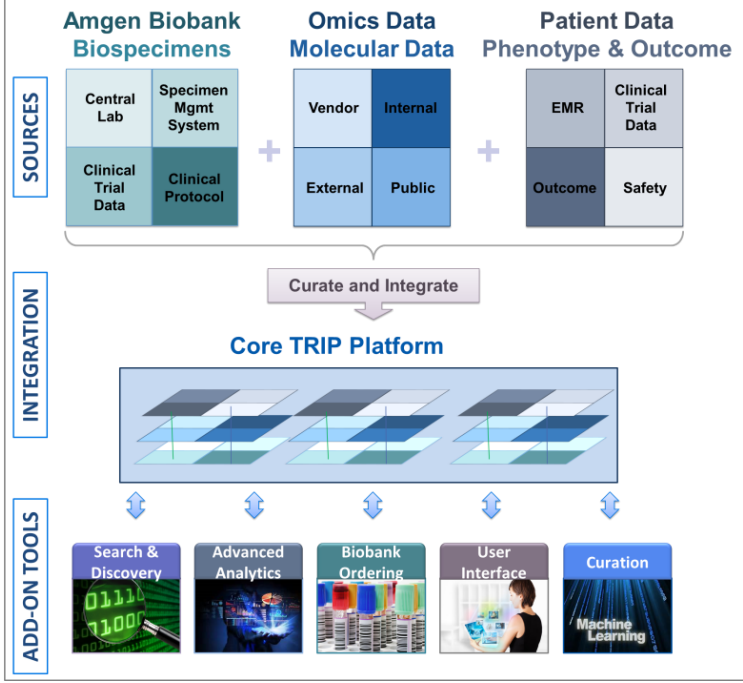
TRIP OVERVIEW

Conceptual Overview



Platform and Tools

- Research Trust data repository, functional data warehouse and analytics, purpose built datamarts
- Search: Basic, Natural language, next generation data discovery and search capabilities
- Advanced Analytics, Visualization, Modeling and Simulation
- Machine Learning enabled automated data curation
- Cohort Integrator to link search and analytics
- Heterogeneous data types

User Experience is a Guiding Principle

- Intuitive, self-service experience
- Balance experience to support novice users and enable complex needs of advanced users.
- Deliver continuous incremental business value
- Enable data driven answers to Scientific questions

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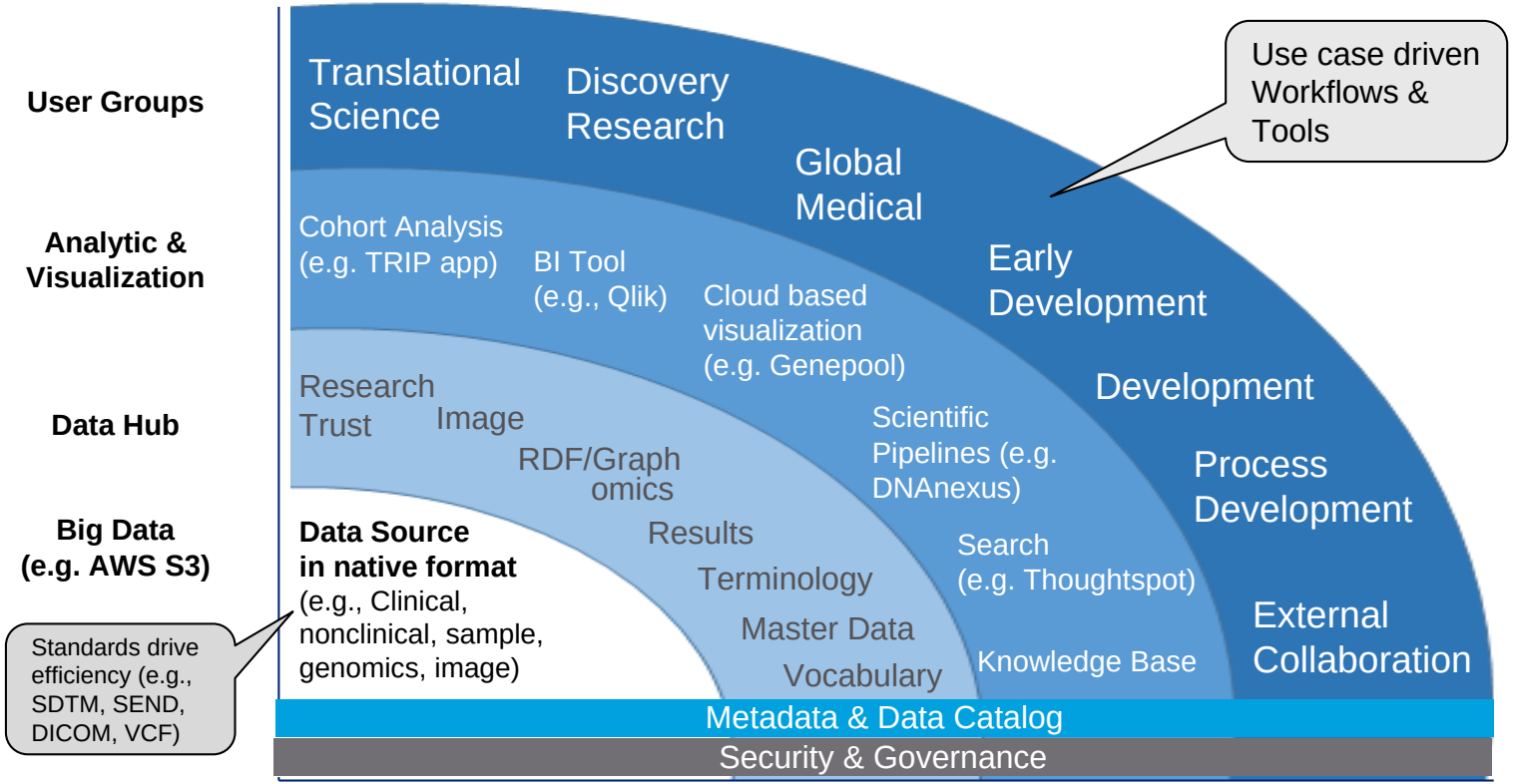
TRIP LOGICAL DATA TIERS



PREREQUISITES FOR SUCCESS:

Strategic implementation of capabilities over the past 5 years

Foundational Information Technology

- Transition to new IT solution enables sophisticated capabilities in Trial management and data/system integration

Data Standardization

- Clinical Data Management implementation of CDISC standards for clinical trial data and metadata in 2009

Data and System Integration

- Integrate external Biobank Inventory & Central Lab Data Feeds with internal systems
- Integrate Clinical Trial data systems with Translational Science systems
- Aggregate non-clinical study data into a data repository using the CDISC SEND standard

Informed Consent

- Collection of Informed Consent standardized and automated
- Consent information integrated with Biobank specimen data

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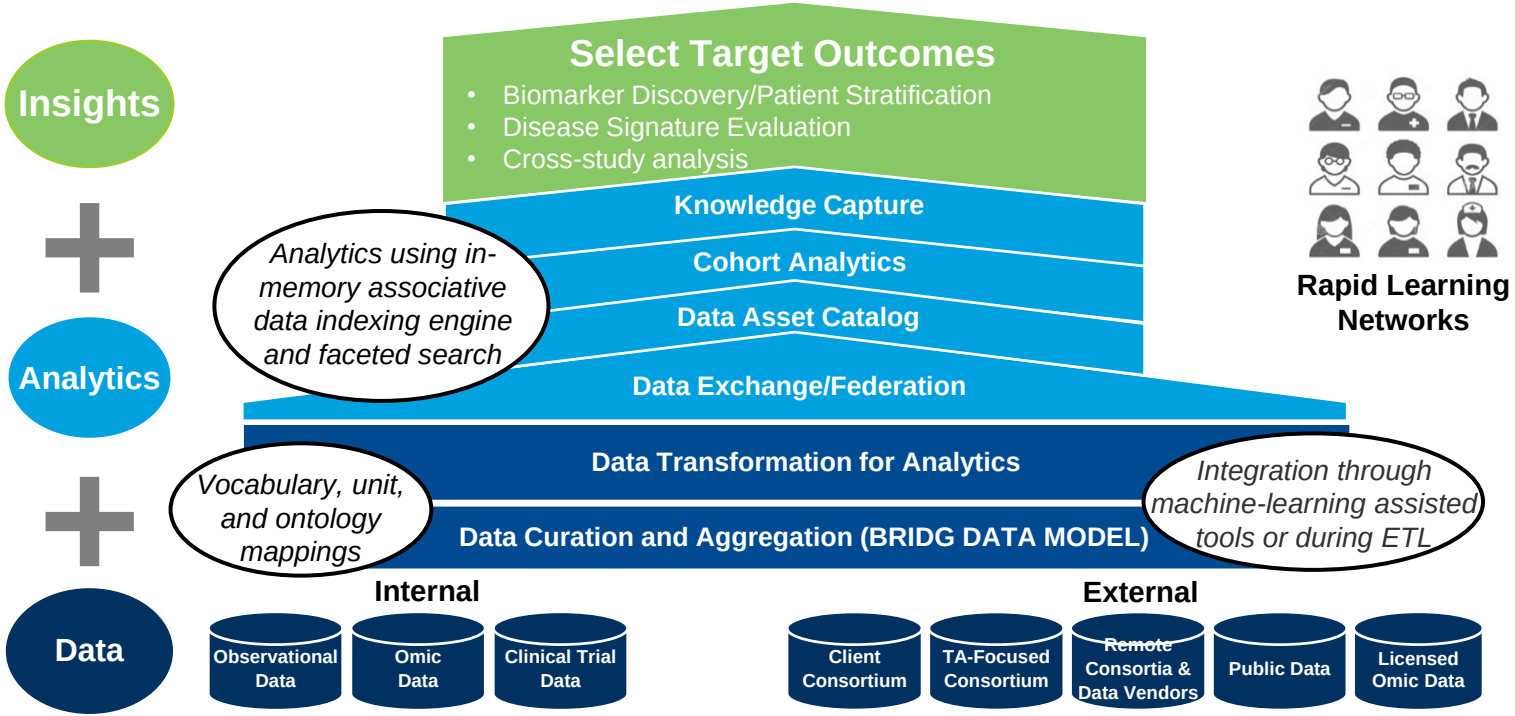
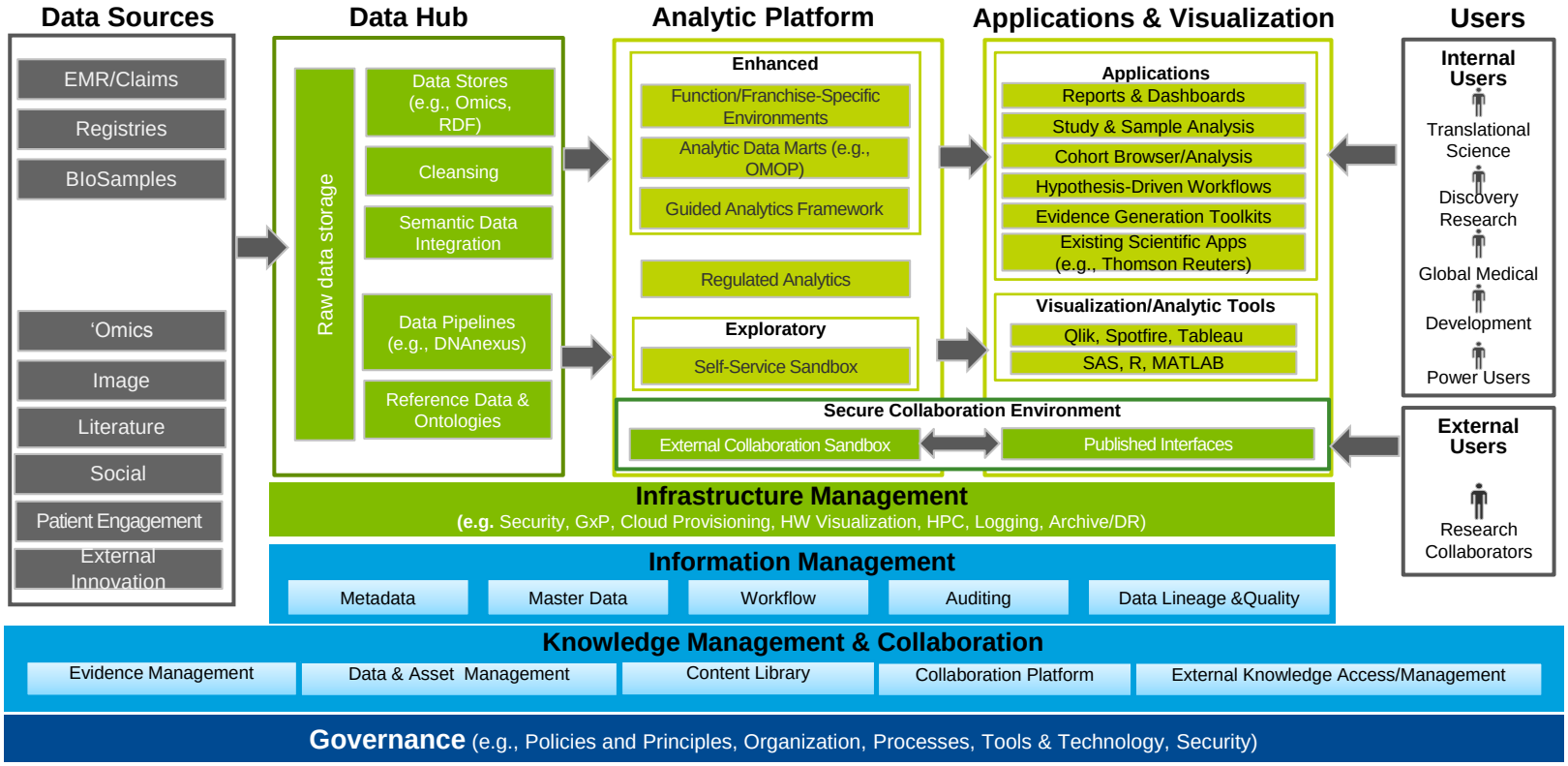
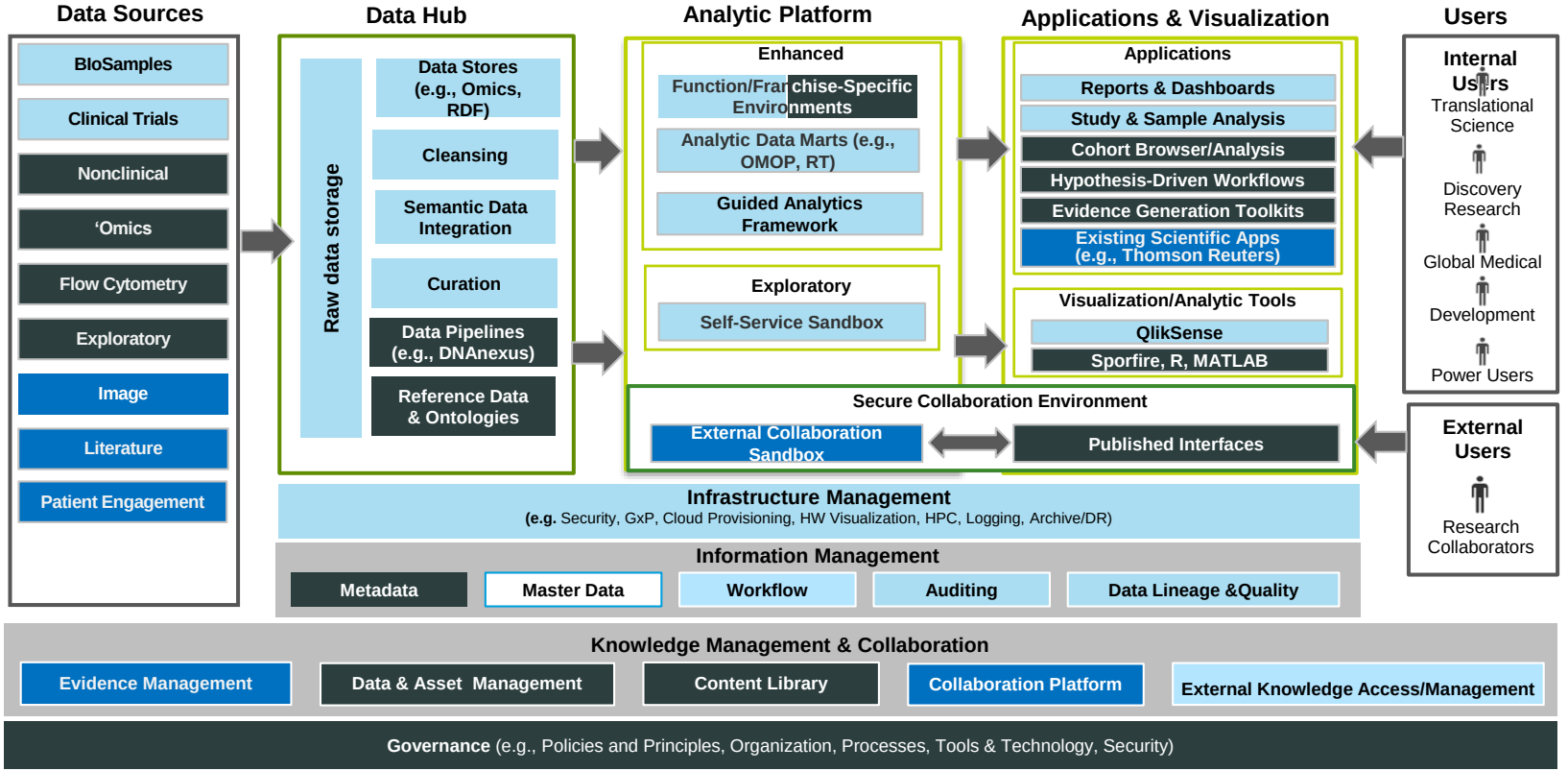
TRANSFORMATION: FROM "WEEKS OF WORK TO MINUTES": ANSWERING CRITICAL QUESTIONS OF RESEARCH TEAMS



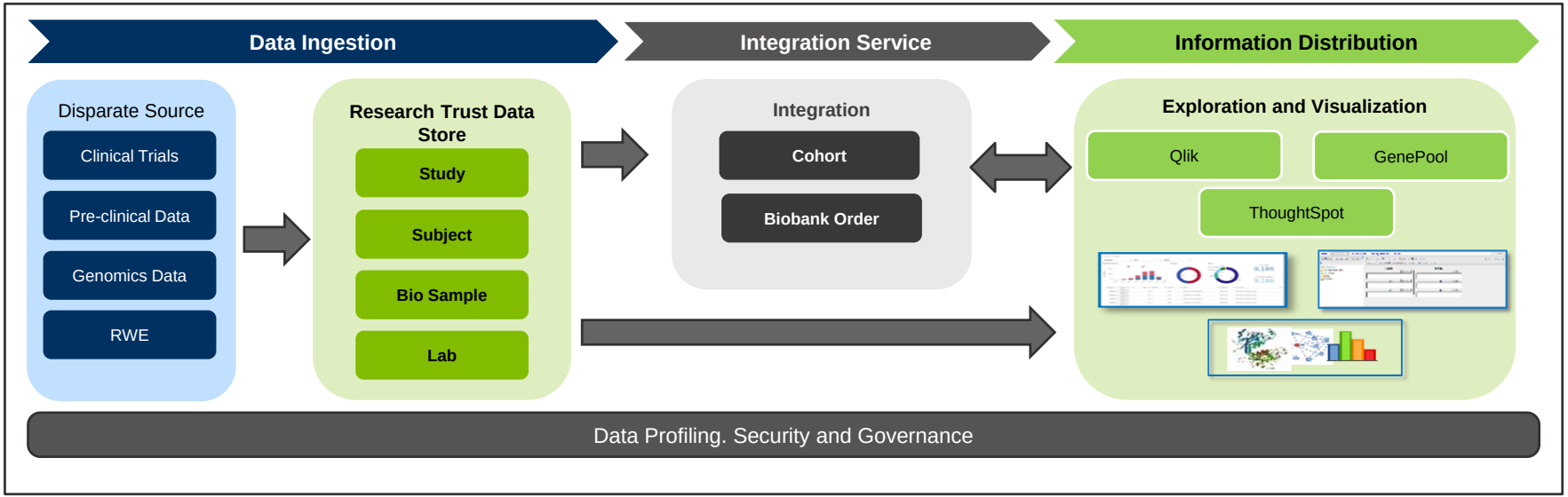
DELOITTE REFERENCE ARCHITECTURE FOR TRANSLATIONAL RESEARCH



AMGEN TARGET ARCHITECTURE – TRANSLATIONAL RESEARCH PLATFORM



CURRENT STATE THREE-TIER ARCHITECTURE



Research Trust is a Deloitte designed BRIDG compliant data model for Clinical Study data

An advanced Translational Research information platform with a user-experience optimized to access heterogeneous Clinical Trials and Molecular data that is harmonized in a standards-based central data repository

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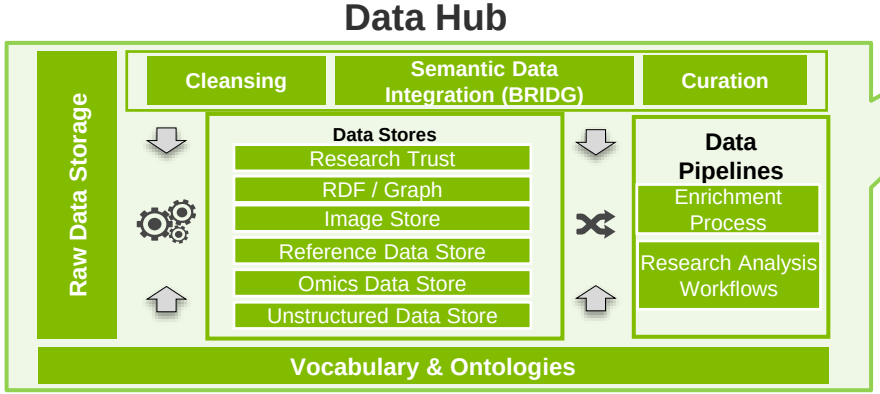
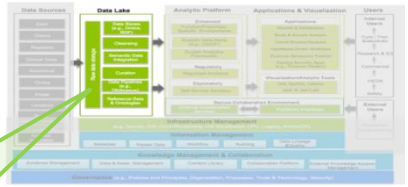
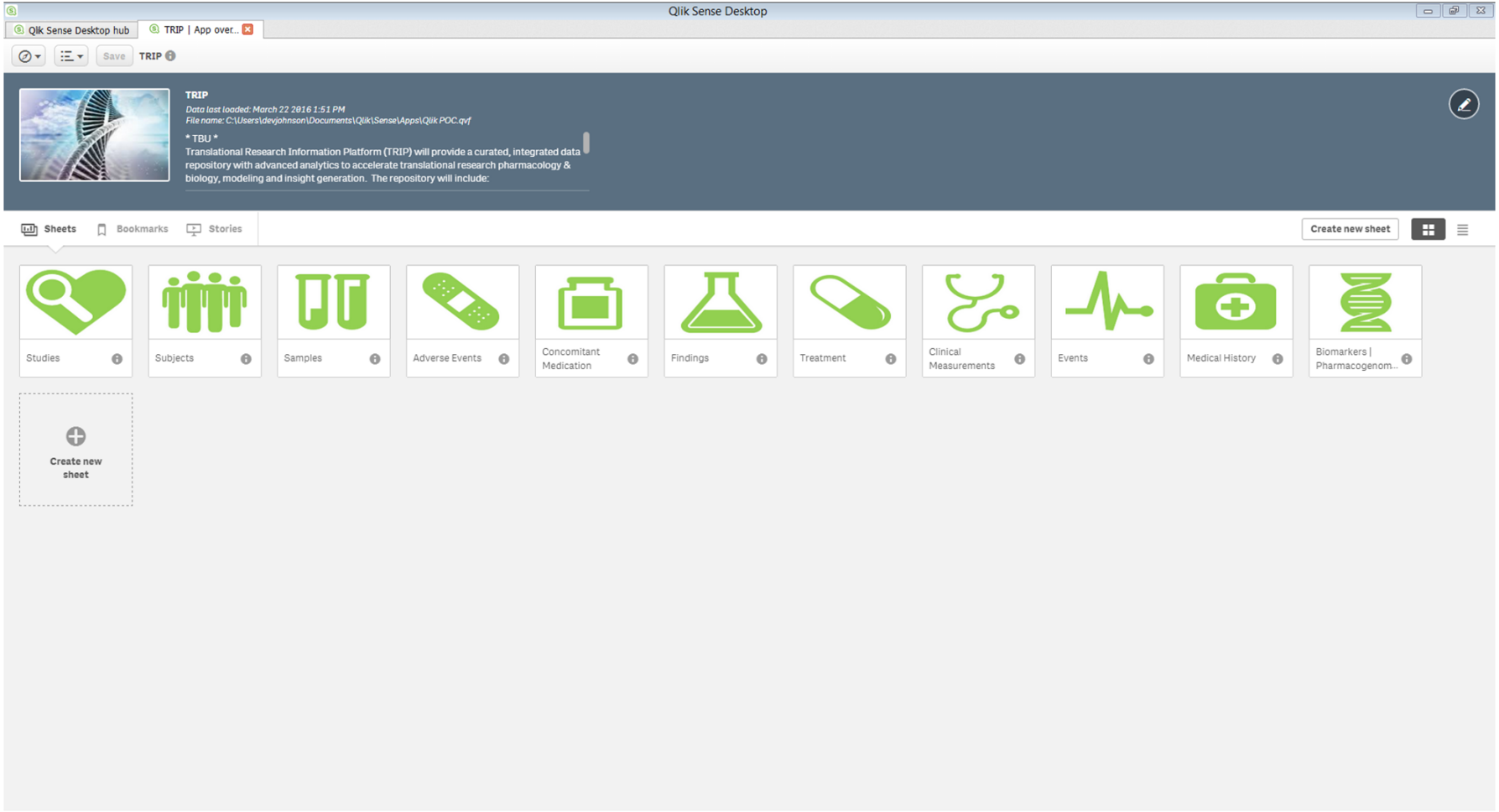
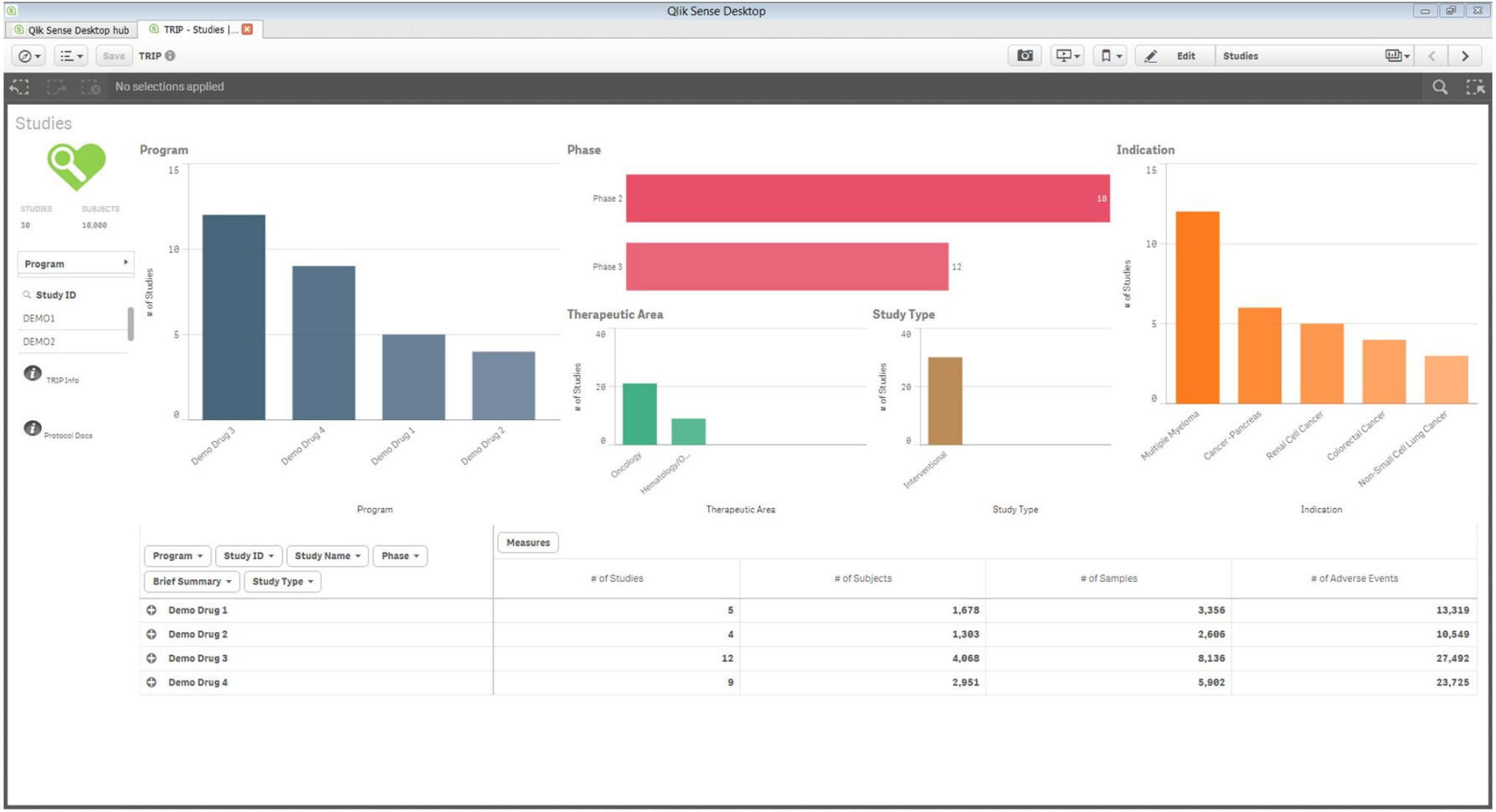
DATA HUB

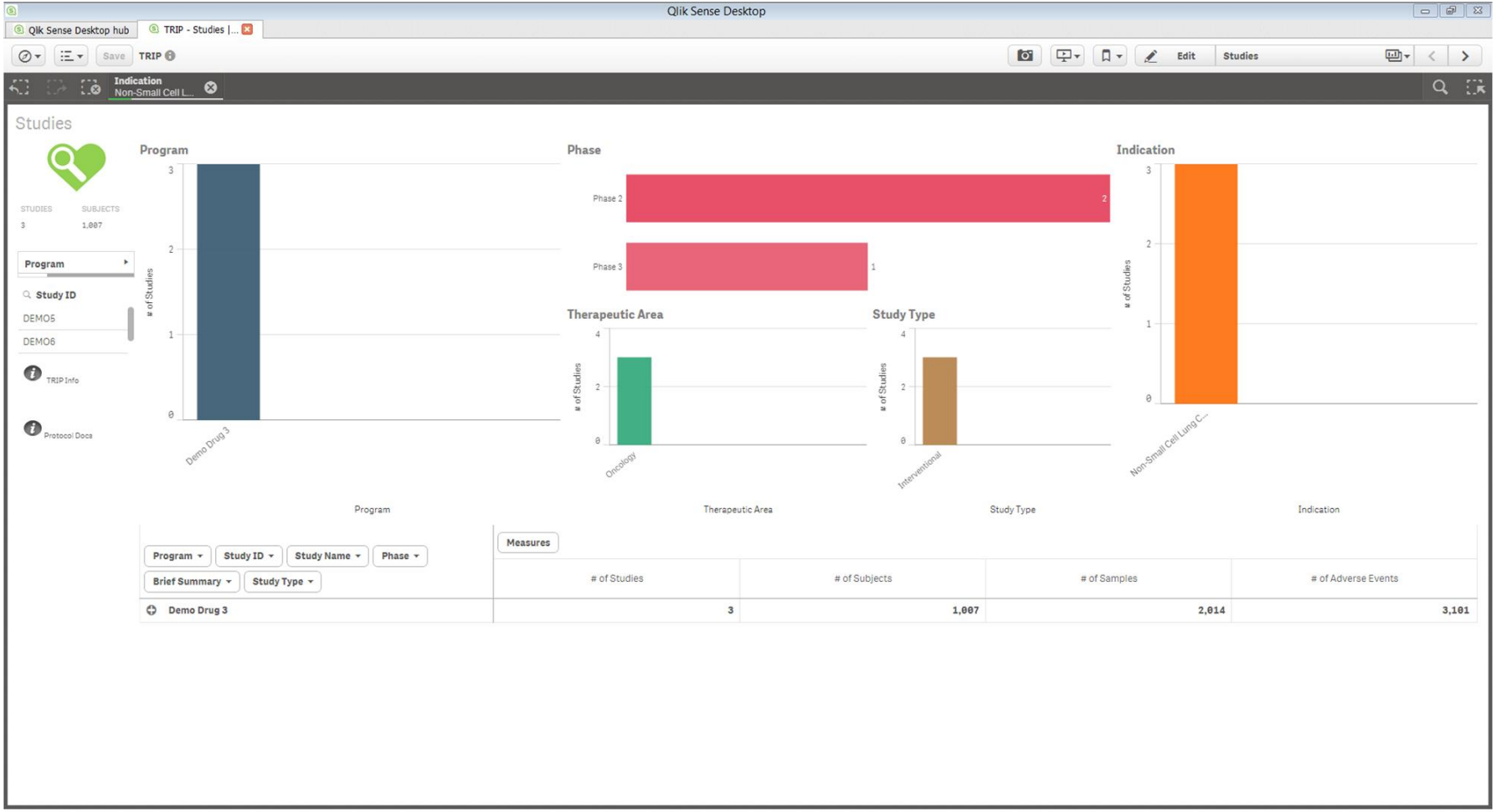


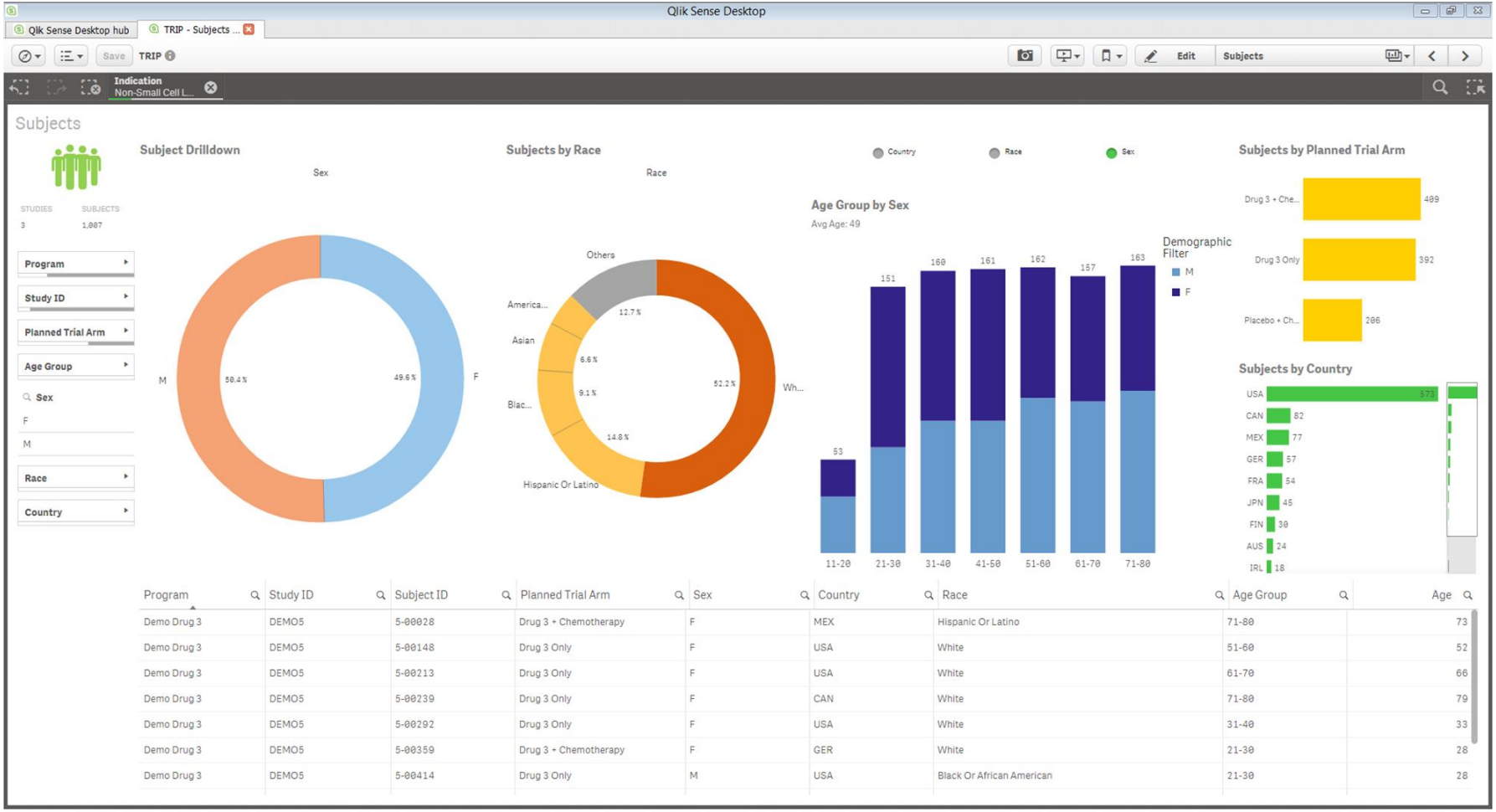


Functionality Provided	Provides a repository to bring in large amounts of data in its native format from disparate sources and organize, integrate, and prepare the data for use by the other architecture components and applications.
Key Requirements	1. Data environment that can support data from multiple sources (SDTM, SEND, Biobank, etc) 2. Ability to scale storage and computing linearly and support growth for vast data volumes 3. Ability to curate, integrate, and enrich datasets from various data sources 4. Ability to capture and manage master data, metadata, and workflows 5. Ability to map data to BRIDG standards and make it accessible via API or direct connection 6. Ability to make data available for tools and nascent queries to support large scale analytics
Primary Technologies/Vendors	**ConvergeHealth:** Research Trust **Tamr:** Machine Learning Data Mapping **DNAnexus:** Omic Pipelines **GenePool:** Omic Analytics/storage

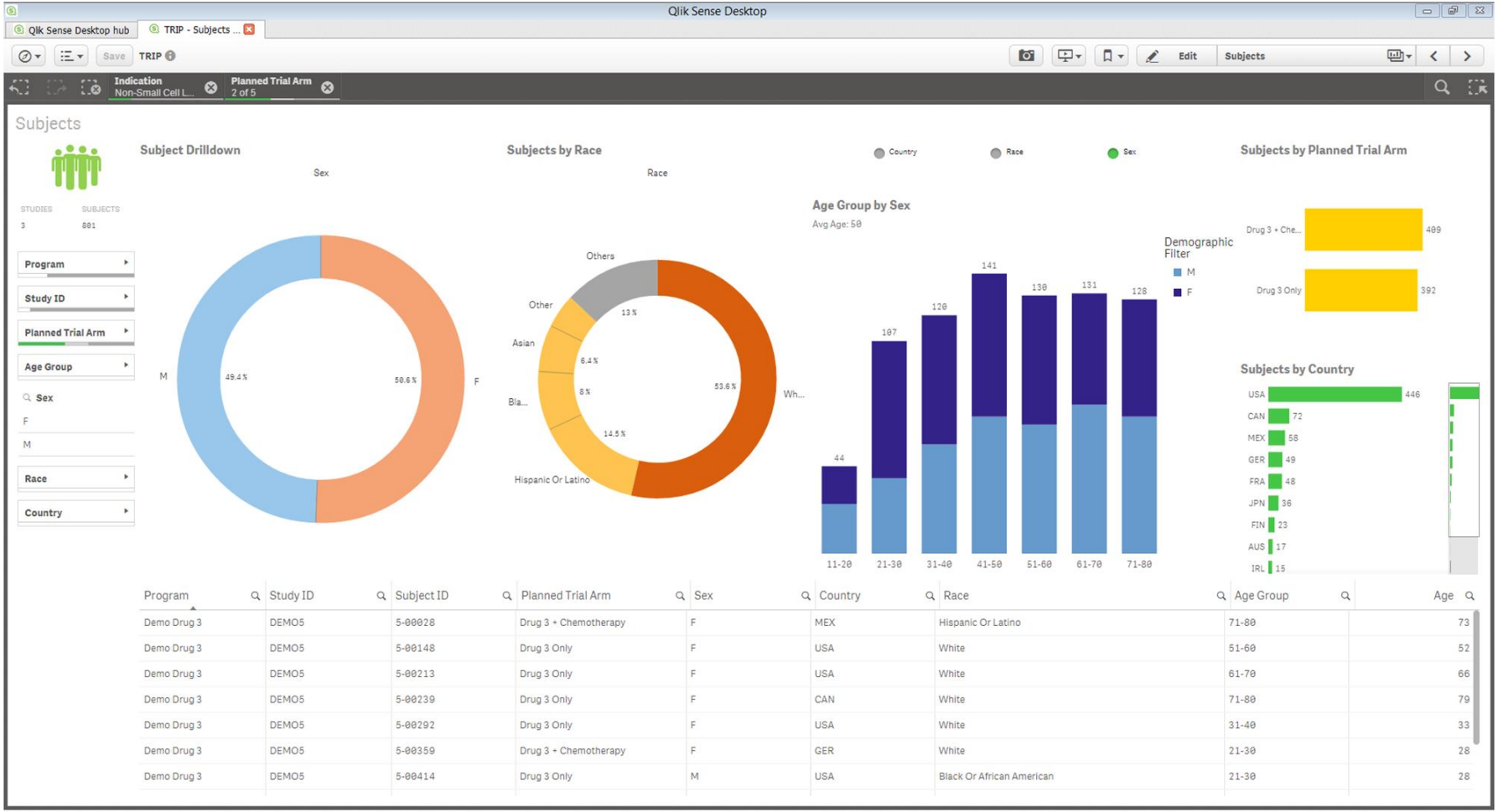

Qlik Sense Desktop
Qlik Sense Desktop hub
TRIP | App over...
Save
TRIP
TRIP
Data last loaded: March 22 2016 1:51 PM
File name: C:\Users\devjohnson\Documents\Qlik\Sense\Apps\Qlik POC.qvf
* TBU *
Translational Research Information Platform (TRIP) will provide a curated, integrated data repository with advanced analytics to accelerate translational research pharmacology & biology, modeling and insight generation. The repository will include:
Sheets
Bookmarks
Stories
Create new sheet
Studies
Subjects
Samples
Adverse Events
Concomitant Medication
Findings
Treatment
Clinical Measurements
Events
Medical History
Biomarkers | Pharmacogenom...
Create new sheet







Program	Study ID	Subject ID	Planned Trial Arm	Sex	Country	Race	Age Group	Age
Demo Drug 3	DEMO5	5-00028	Drug 3 + Chemotherapy	F	MEX	Hispanic Or Latino	71-80	73
Demo Drug 3	DEMO5	5-00148	Drug 3 Only	F	USA	White	51-60	52
Demo Drug 3	DEMO5	5-00213	Drug 3 Only	F	USA	White	61-70	66
Demo Drug 3	DEMO5	5-00239	Drug 3 Only	F	CAN	White	71-80	79
Demo Drug 3	DEMO5	5-00292	Drug 3 Only	F	USA	White	31-40	33
Demo Drug 3	DEMO5	5-00359	Drug 3 + Chemotherapy	F	GER	White	21-30	28
Demo Drug 3	DEMO5	5-00414	Drug 3 Only	M	USA	Black Or African American	21-30	28



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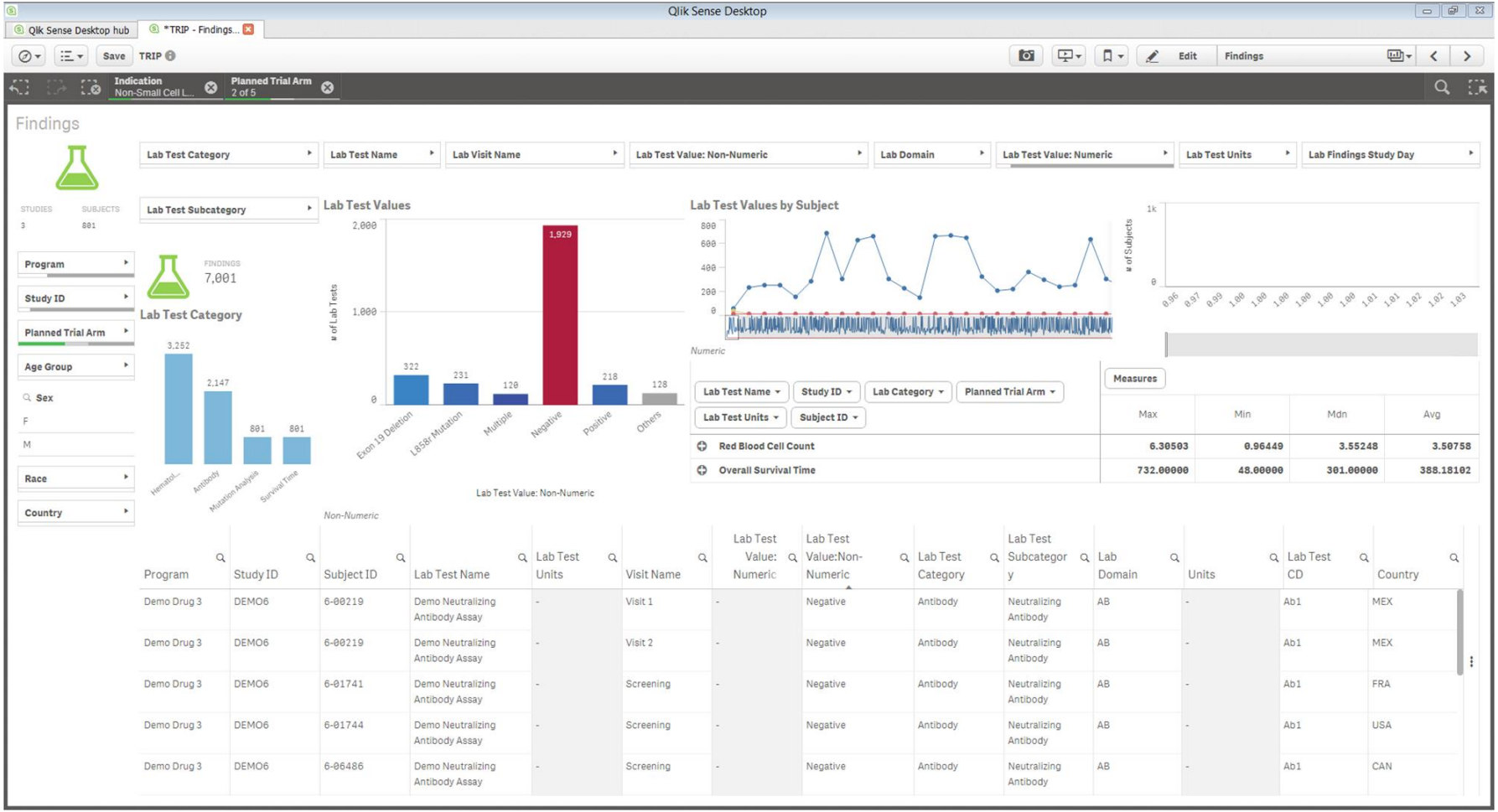
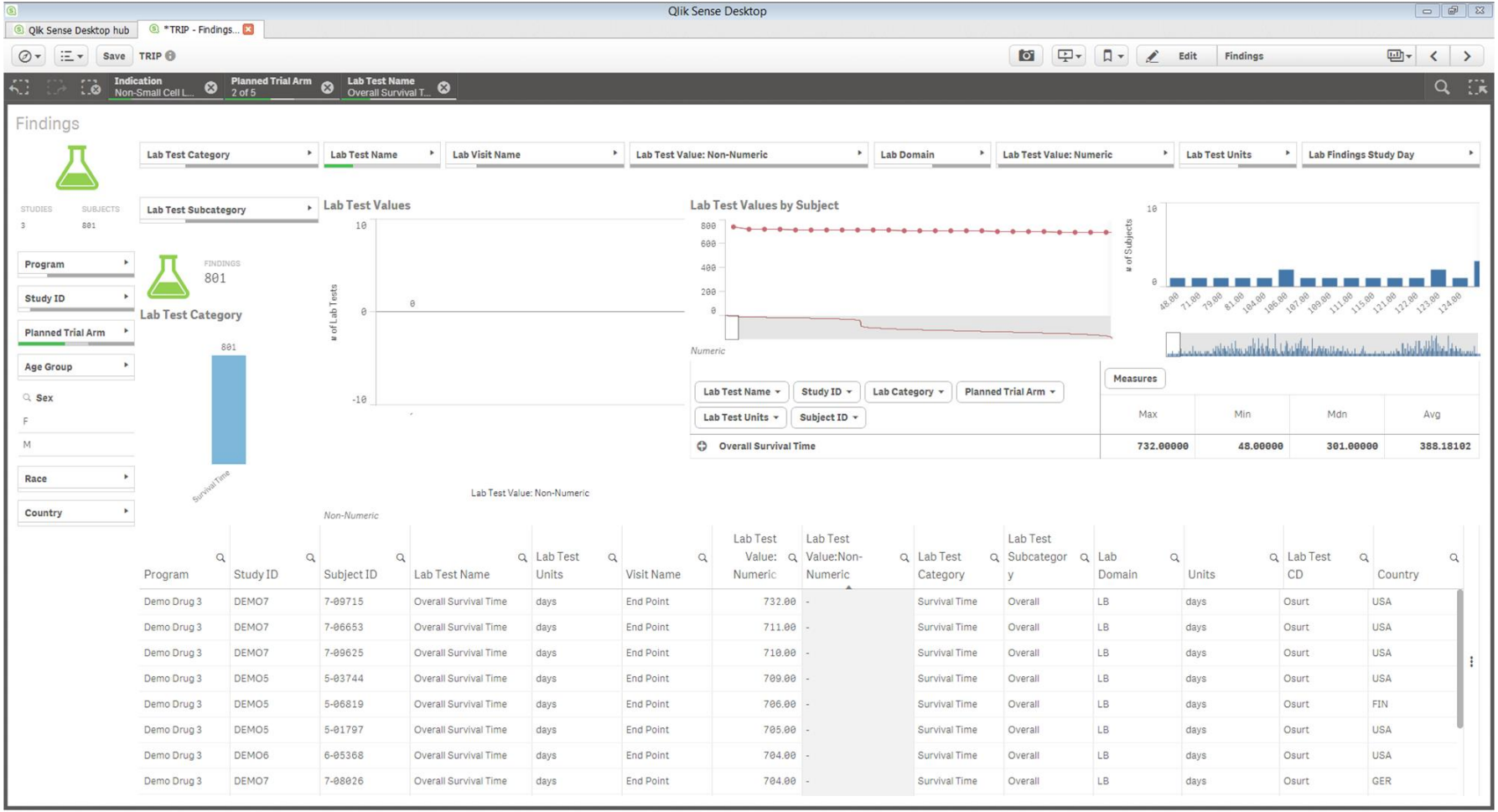
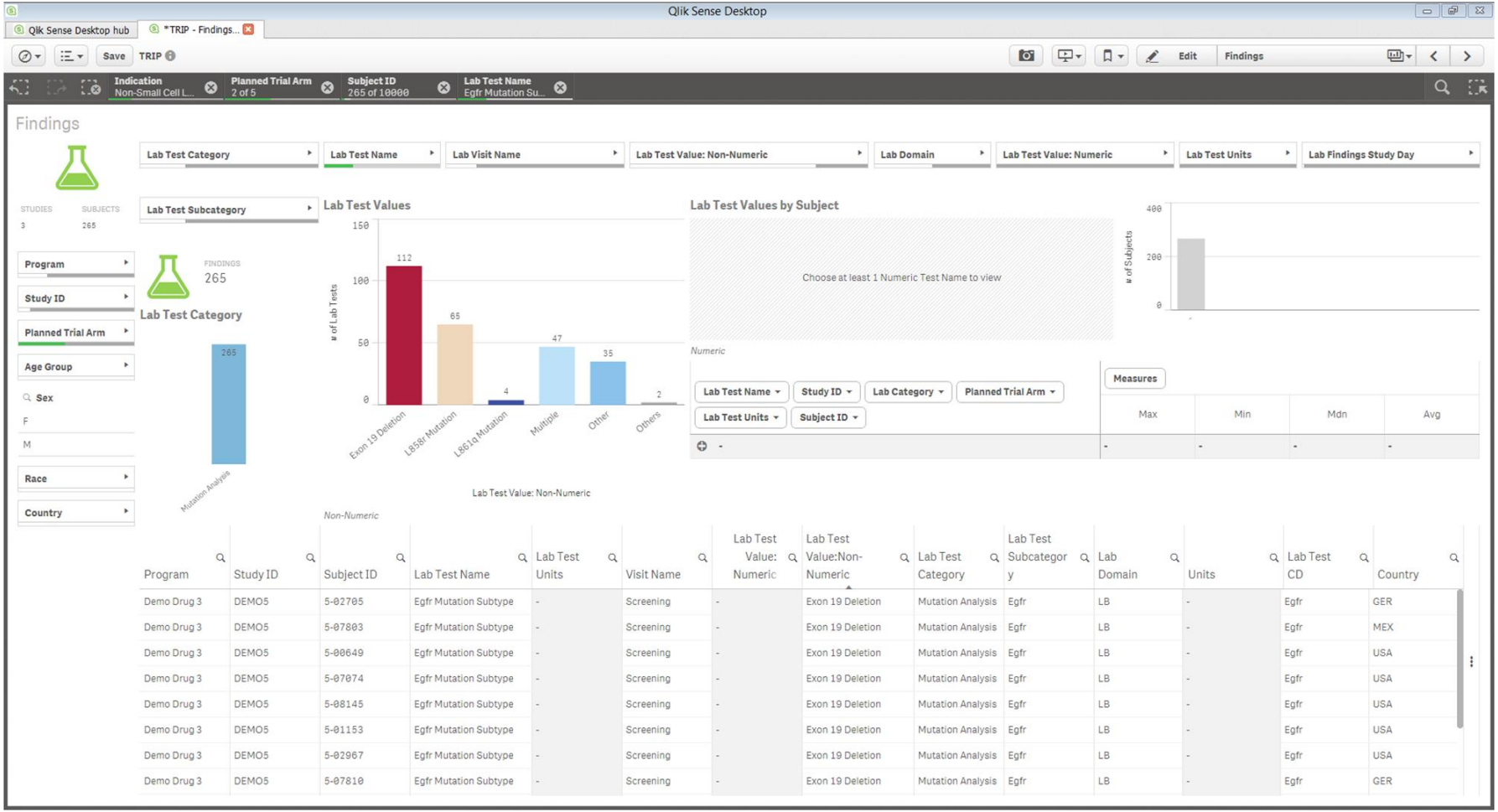
Demo Drug 3	DEMO5	5-00414	Drug 3 Only	M	USA	Black Or African American	21-30	28

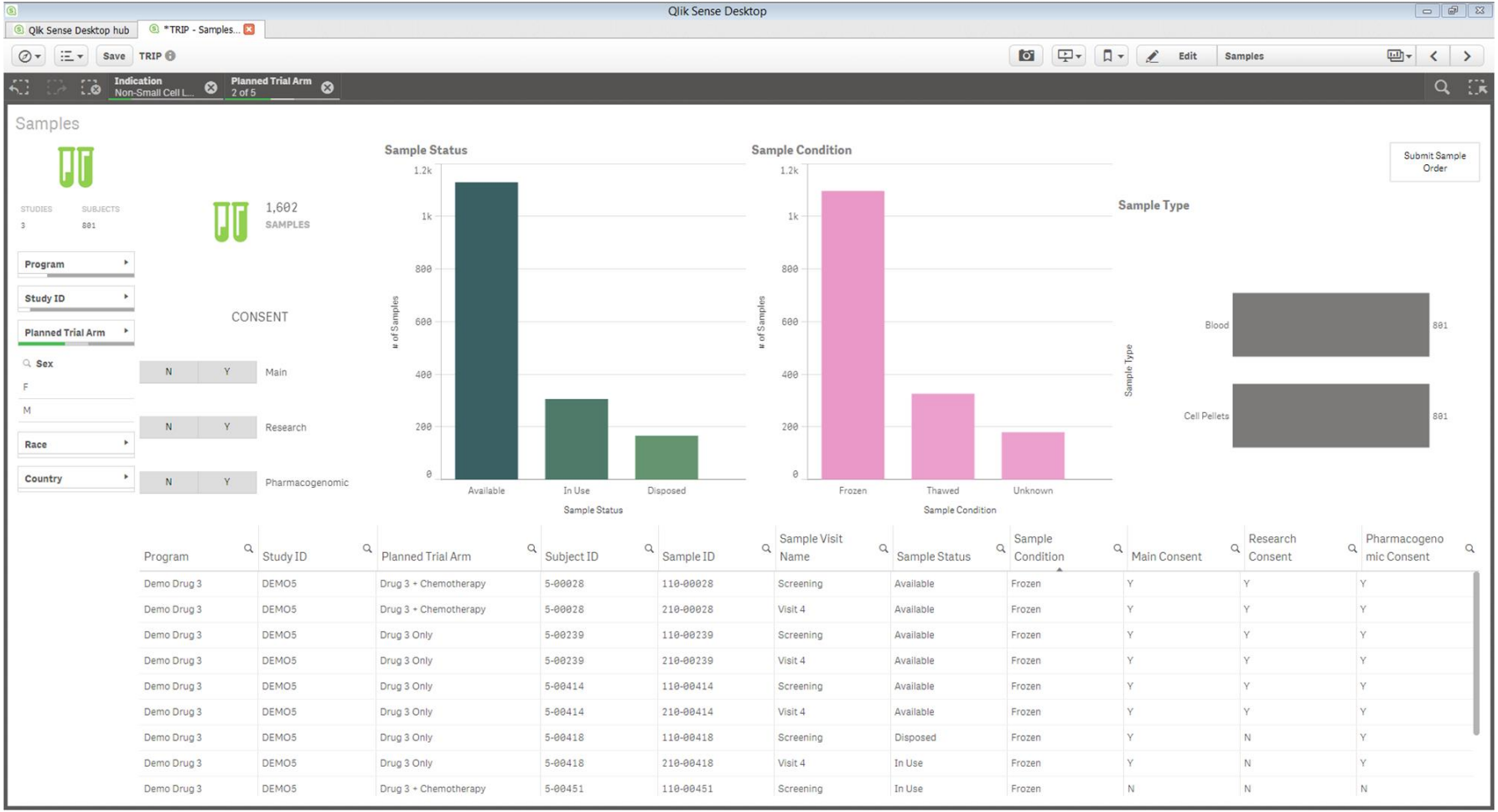
Simulated Data



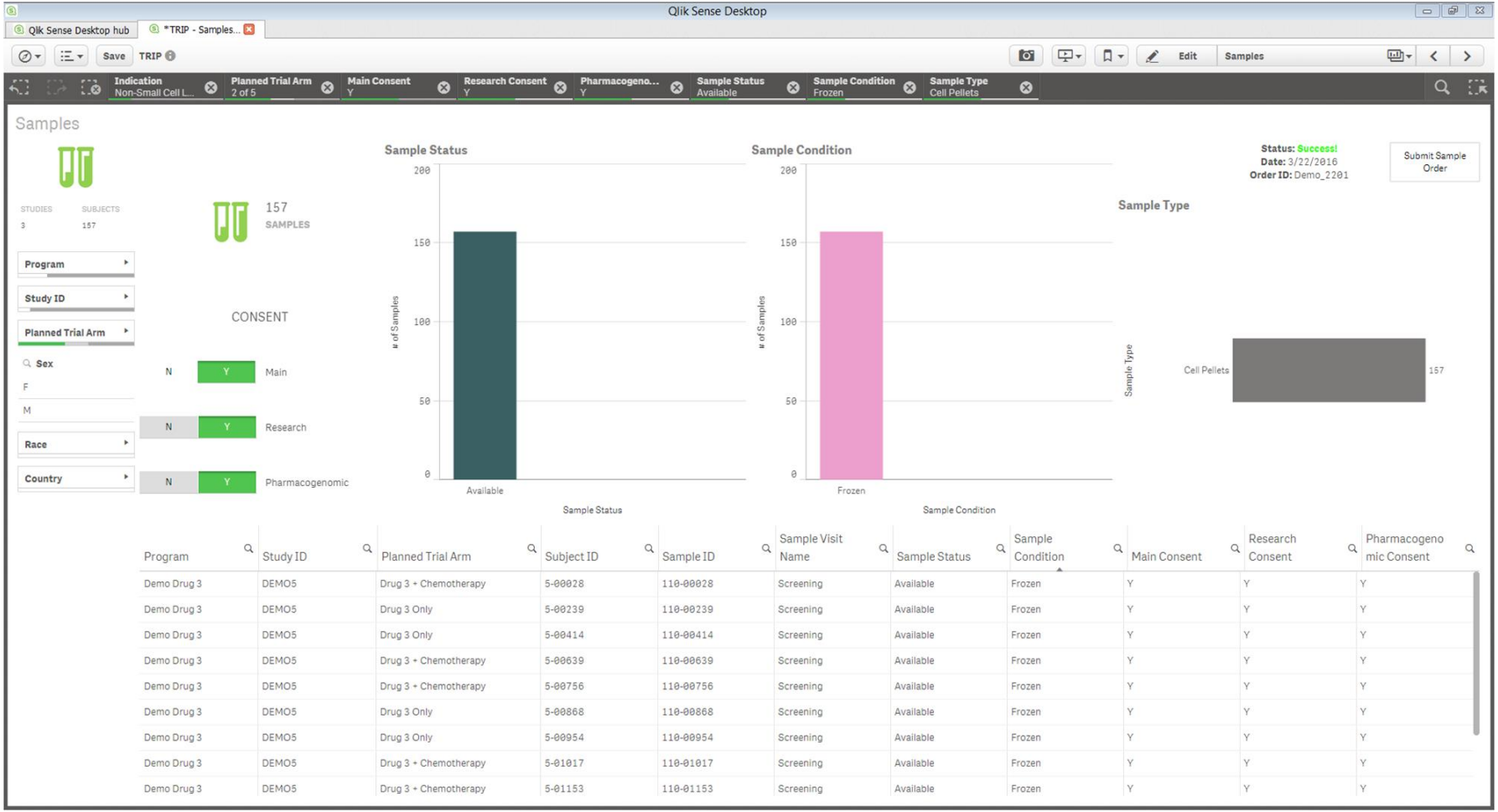


Program	Study ID	Subject ID	Lab Test Name	Lab Test Units	Visit Name	Lab Test Value: Numeric	Lab Test Value:Non-Numeric	Lab Test Category	Lab Test Subcategory	Lab Domain	Units	Lab Test CD	Country
Demo Drug 3	DEMO7	7-09715	Overall Survival Time	days	End Point	732.00	-	Survival Time	Overall	LB	days	Osurt	USA
Demo Drug 3	DEMO7	7-06653	Overall Survival Time	days	End Point	711.00	-	Survival Time	Overall	LB	days	Osurt	USA
Demo Drug 3	DEMO7	7-09625	Overall Survival Time	days	End Point	710.00	-	Survival Time	Overall	LB	days	Osurt	USA
Demo Drug 3	DEMO5	5-03744	Overall Survival Time	days	End Point	709.00	-	Survival Time	Overall	LB	days	Osurt	USA
Demo Drug 3	DEMO5	5-06819	Overall Survival Time	days	End Point	706.00	-	Survival Time	Overall	LB	days	Osurt	FIN
Demo Drug 3	DEMO5	5-01797	Overall Survival Time	days	End Point	705.00	-	Survival Time	Overall	LB	days	Osurt	USA
Demo Drug 3	DEMO6	6-05368	Overall Survival Time	days	End Point	704.00	-	Survival Time	Overall	LB	days	Osurt	USA
Demo Drug 3	DEMO7	7-08026	Overall Survival Time	days	End Point	704.00	-	Survival Time	Overall	LB	days	Osurt	GER





Program	Study ID	Planned Trial Arm	Subject ID	Sample ID	Sample Visit Name	Sample Status	Sample Condition	Main Consent	Research Consent	Pharmacogenomic Consent
Demo Drug 3	DEMO5	Drug 3 + Chemotherapy	5-00028	110-00028	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 + Chemotherapy	5-00028	210-00028	Visit 4	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00239	110-00239	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00239	210-00239	Visit 4	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00414	110-00414	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00414	210-00414	Visit 4	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00418	110-00418	Screening	Disposed	Frozen	Y	N	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00418	210-00418	Visit 4	In Use	Frozen	Y	N	Y
Demo Drug 3	DEMO5	Drug 3 + Chemotherapy	5-00451	110-00451	Screening	In Use	Frozen	N	N	N



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Demo Drug 3	DEMO5	Drug 3 + Chemotherapy	5-00028	110-00028	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00239	110-00239	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00414	110-00414	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 + Chemotherapy	5-00639	110-00639	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 + Chemotherapy	5-00756	110-00756	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00868	110-00868	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 Only	5-00954	110-00954	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 + Chemotherapy	5-01017	110-01017	Screening	Available	Frozen	Y	Y	Y
Demo Drug 3	DEMO5	Drug 3 + Chemotherapy	5-01153	110-01153	Screening	Available	Frozen	Y	Y	Y

TRANSLATIONAL RESEARCH INFORMATICS MATURITY MODEL