

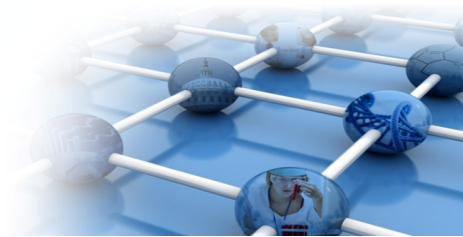


The i2b2/tranSMART Foundation Overview

Diane Keogh, Peter Rice, Shawn Murphy, MD, PhD.
Paul Avillach, MD, PhD

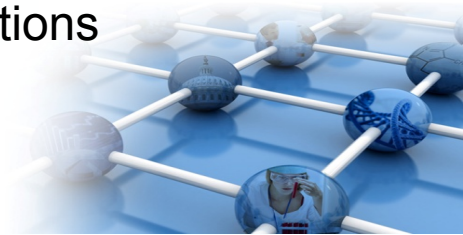
Agenda

- Brief history of tranSMART
- Precision Medicine: The Role of i2b2 and tranSMART
- What does the i2b2 tranSMART Foundation do?
- The importance and role of an Open Source “Community”
- i2b2 tranSMART Governance model
 - Board of Directors
 - Project Management Committees (PMC)
 - Partnership Program
 - Membership Program
- PMC Roadmaps
 - tranSMART – Peter Rice
 - i2b2 – Shawn Murphy
 - i2b2 tranSMART – Paul Avillach



The History of tranSMART

- In 2008: J&J saw a significant challenge in the lack of translatability of preclinical models into meaningful biological knowledge
- They created tranSMART – “a knowledge management platform that would provide access to all R&D data as well as advanced analytics”
- It utilized components of the i2b2 (Informatics for Integrating Biology and the Bedside; <http://www.i2b2.org>) and incorporated search capabilities
- A goal was to release the software as open source to encourage precompetitive data sharing among pharmaceutical entities and academic institutions



tranSMART Foundation Members

Gold Members (5)



Silver Members (15)



Affiliate Members (3)



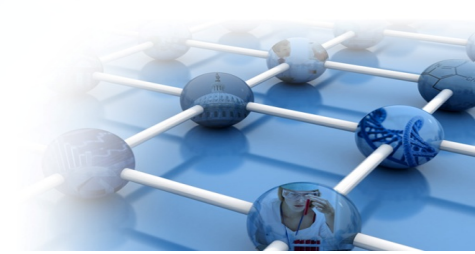
Translational Research



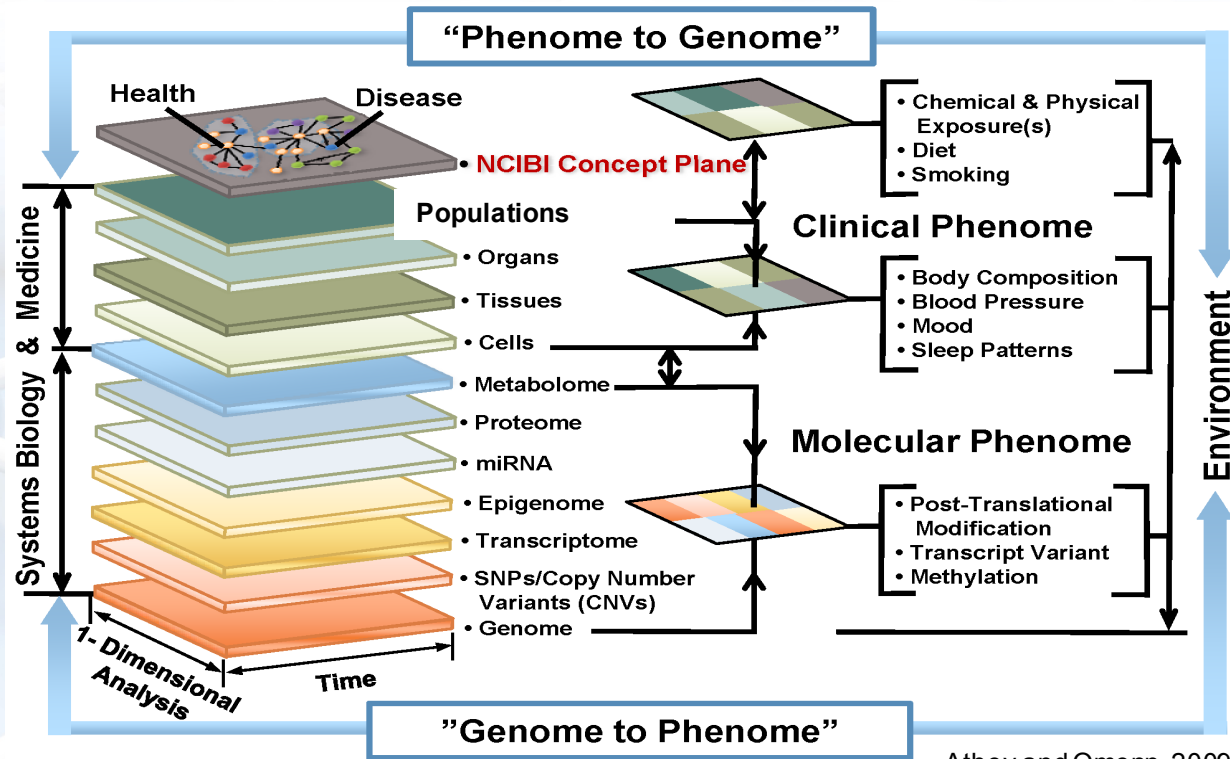
Translational Research is the process of applying ideas, insights, and discoveries generated through basic scientific inquiry to the treatment and prevention of human disease – the critical bridge between basic and clinical research.

The steps in translational research are designed to ensure that the discoveries that advance into human trials have the highest possible chance of success in terms of both safety and efficacy.

Catalyzing Translational Innovation
CHRISTOPHER P. AUSTIN, M.D.
DIRECTOR, NCATS



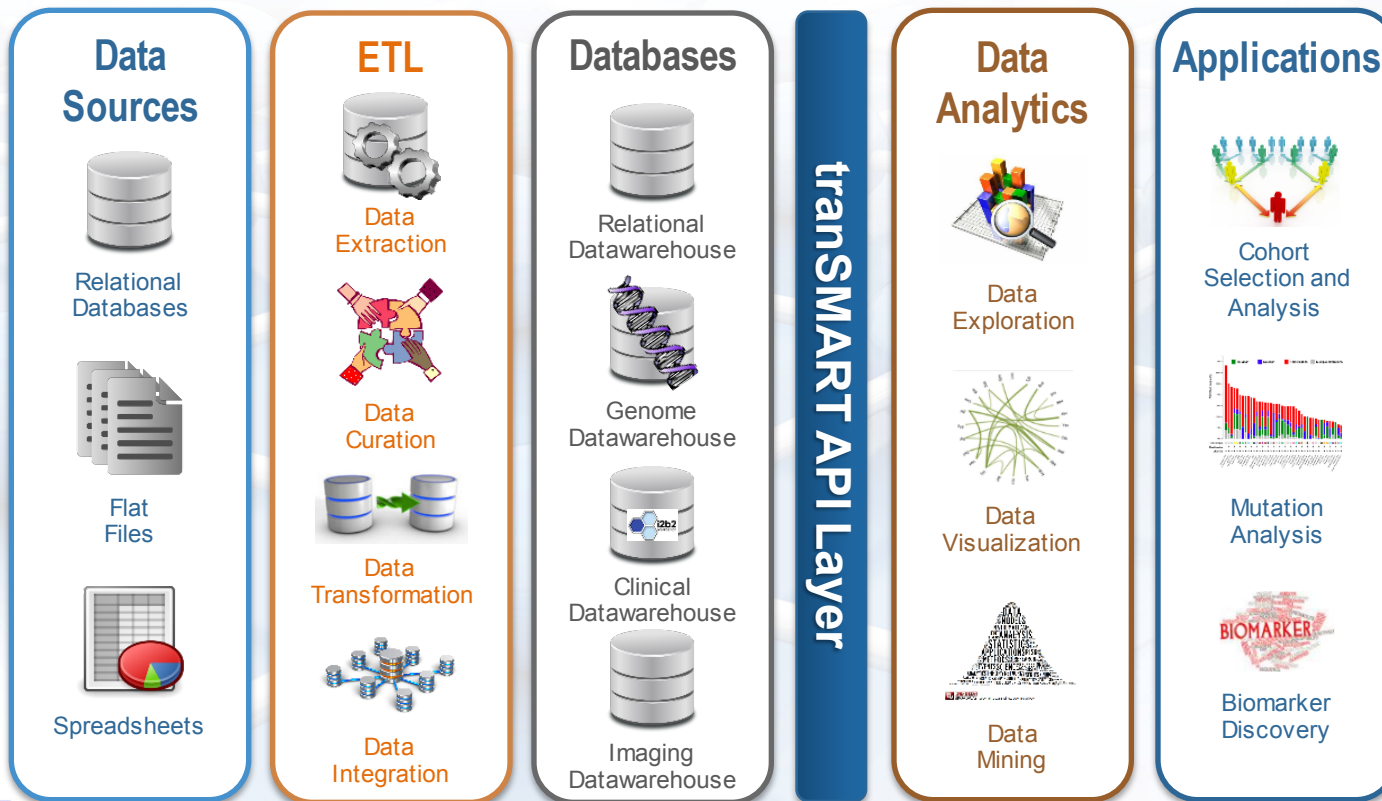
Translational Research Data is Big Data



Athey and Omenn, 2009

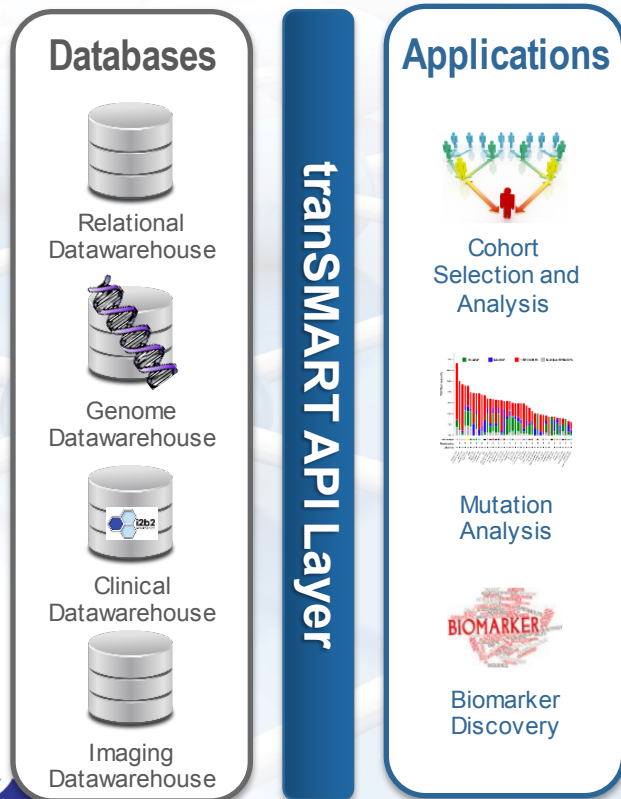
Volume, Variety, Velocity

tranSMART Architecture



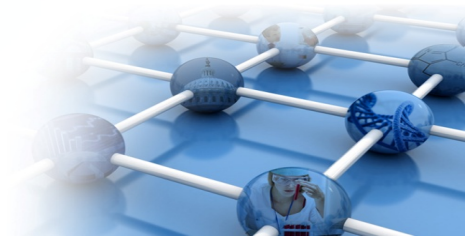
tranSMART: More than just a Platform

an approach to enable translational science



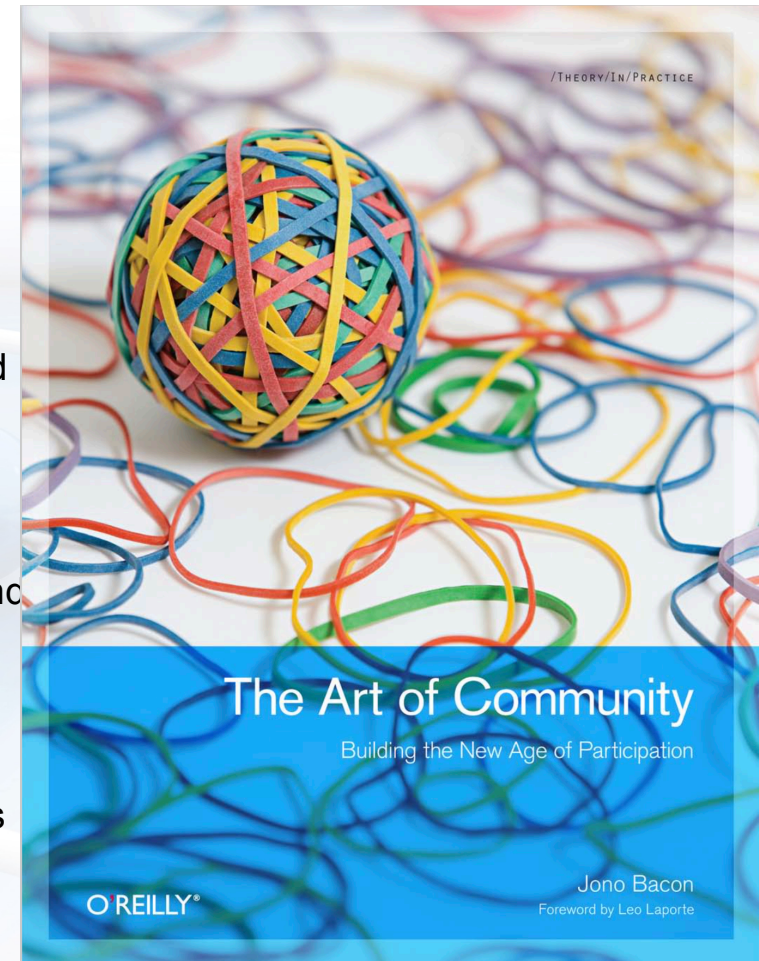
tranSMART – A platform and Community

- Open-source and open-data translational biomedical research community
- Scientists, Developers, Service Providers, Clinicians



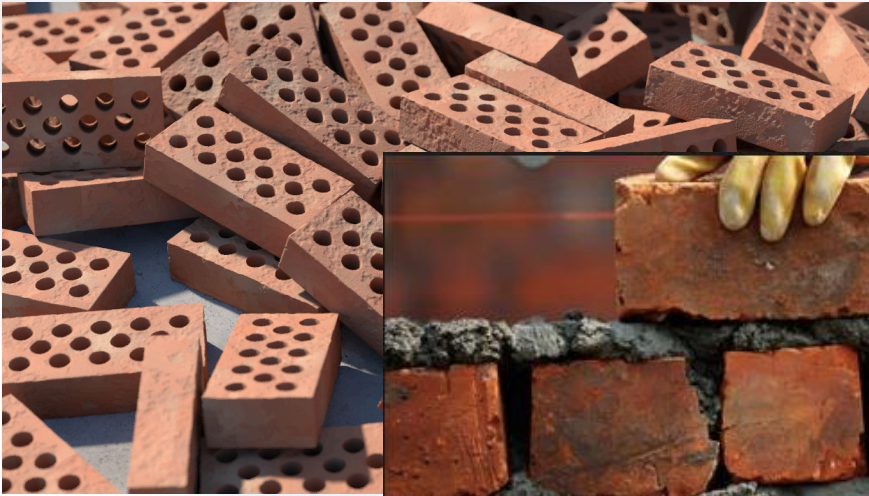
The Art of Community

- Building a community
 - Develop a strategy and goals for building your community
 - Provide tools and infrastructure to help contributors
 - Create “buzz” around your community to get more people involved
- Attributes of an open source community
 - Transparency of community process, and discussion
 - Competition is fostered – what fixes and features are accepted, and what ones don't make it
- What makes a community work
 - A sense of belonging is what keeps people in the community. This belonging is a goal of the community

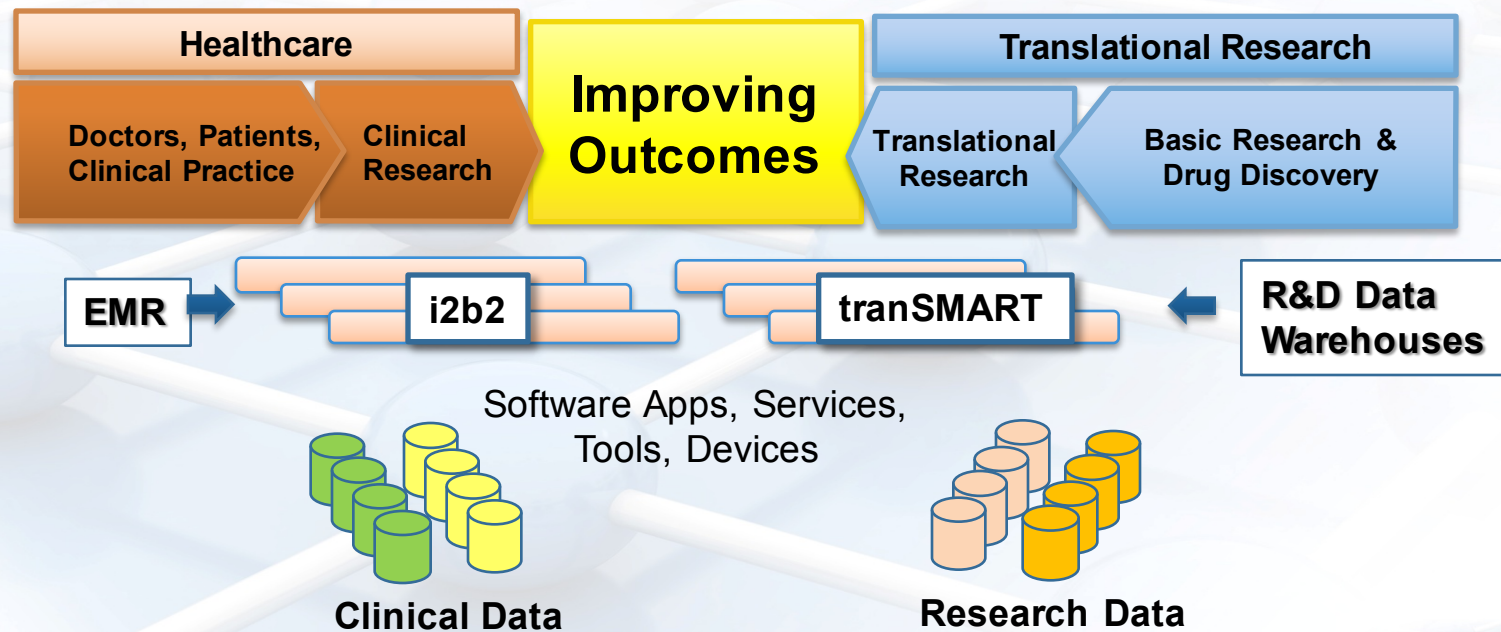


The 'Mortar between the Bricks'

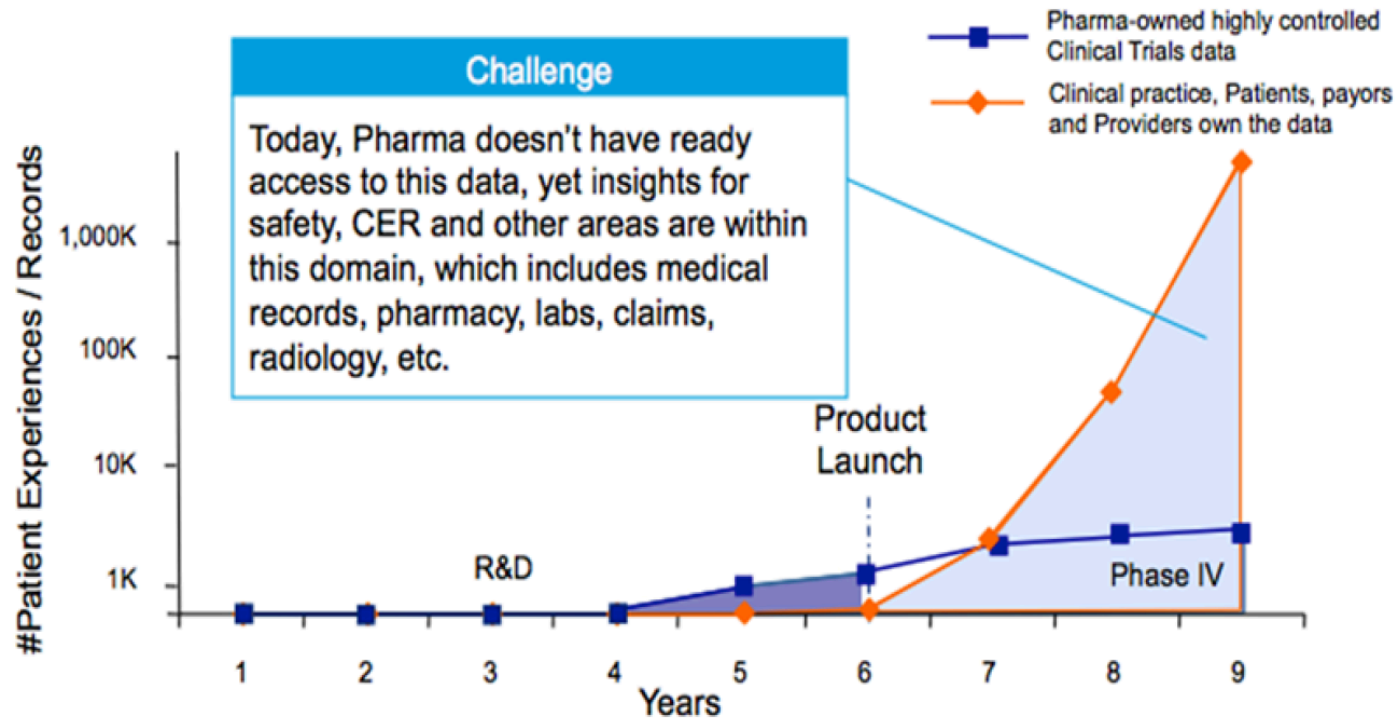
- The Foundation provides the structure that links the community members together, to build a strong community and platform



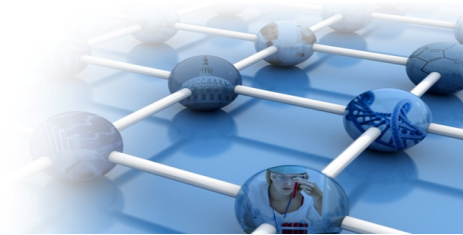
Precision Medicine = Clinical Care + Translational Research



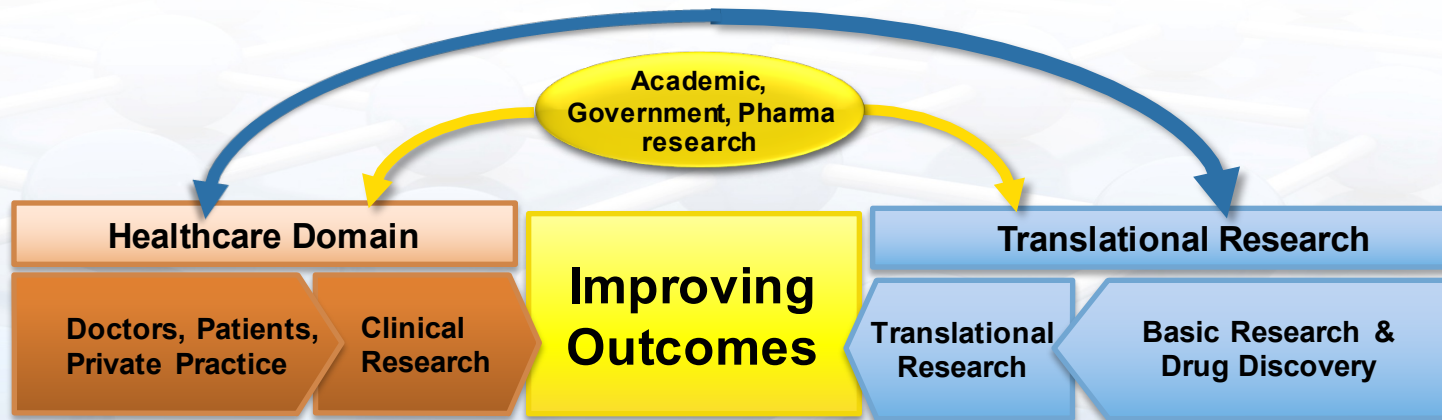
The Value of Patient Data



The value of healthcare data for secondary uses in clinical research and development
Gary K. Mallow, Ph.D. Merrk, HIMMS 2012



Precision Medicine: Translational Research + Healthcare

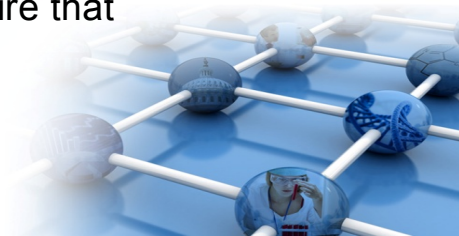


“The future of precision medicine will enable health care providers to tailor treatment and prevention strategies to people’s unique characteristics, including their genome sequence, microbiome composition, health history, lifestyle, and diet. To get there, we need to incorporate many different types of data, from metabolomics, the microbiome, and data about the patient collected by health care providers and the patients themselves. Success will require that health data is portable, that it can be easily shared between providers, researchers, and most importantly, patients and research participants.”

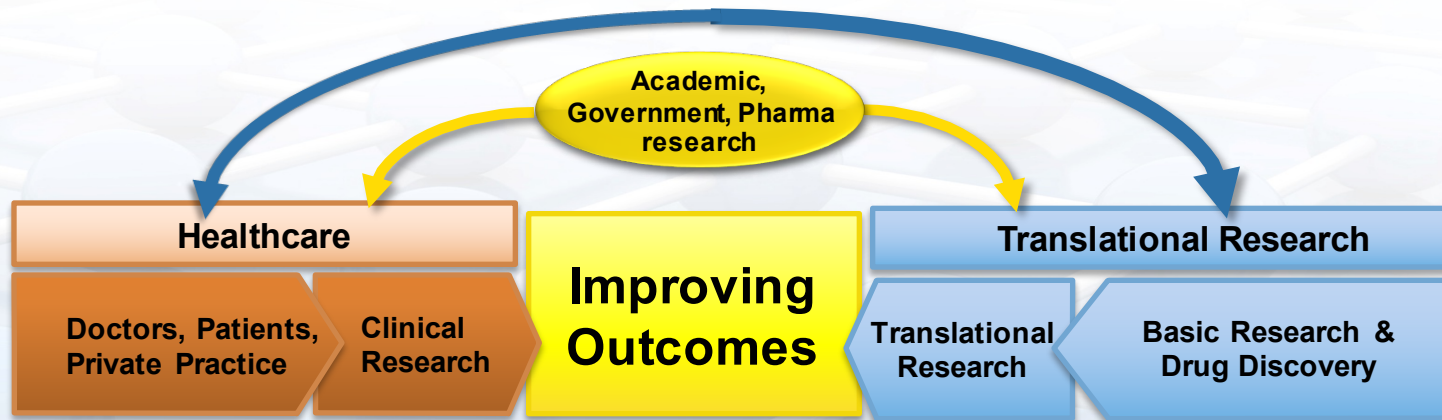


i2b2
tranSMART
FOUNDED

What is the Precision Medicine Initiative? – www.whitehouse.gov/precision-medicine



Precision Medicine: Translational Research + Healthcare

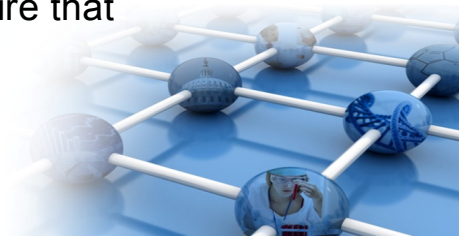


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i2b2
tranSMART
FOUNDED

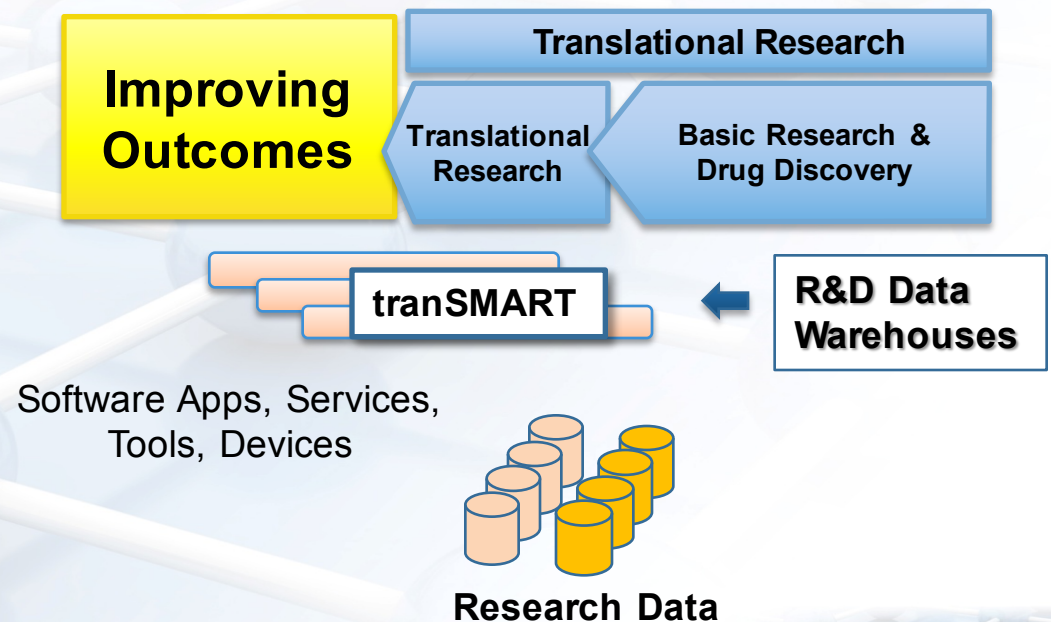
What is the Precision Medicine Initiative? – www.whitehouse.gov/precision-medicine



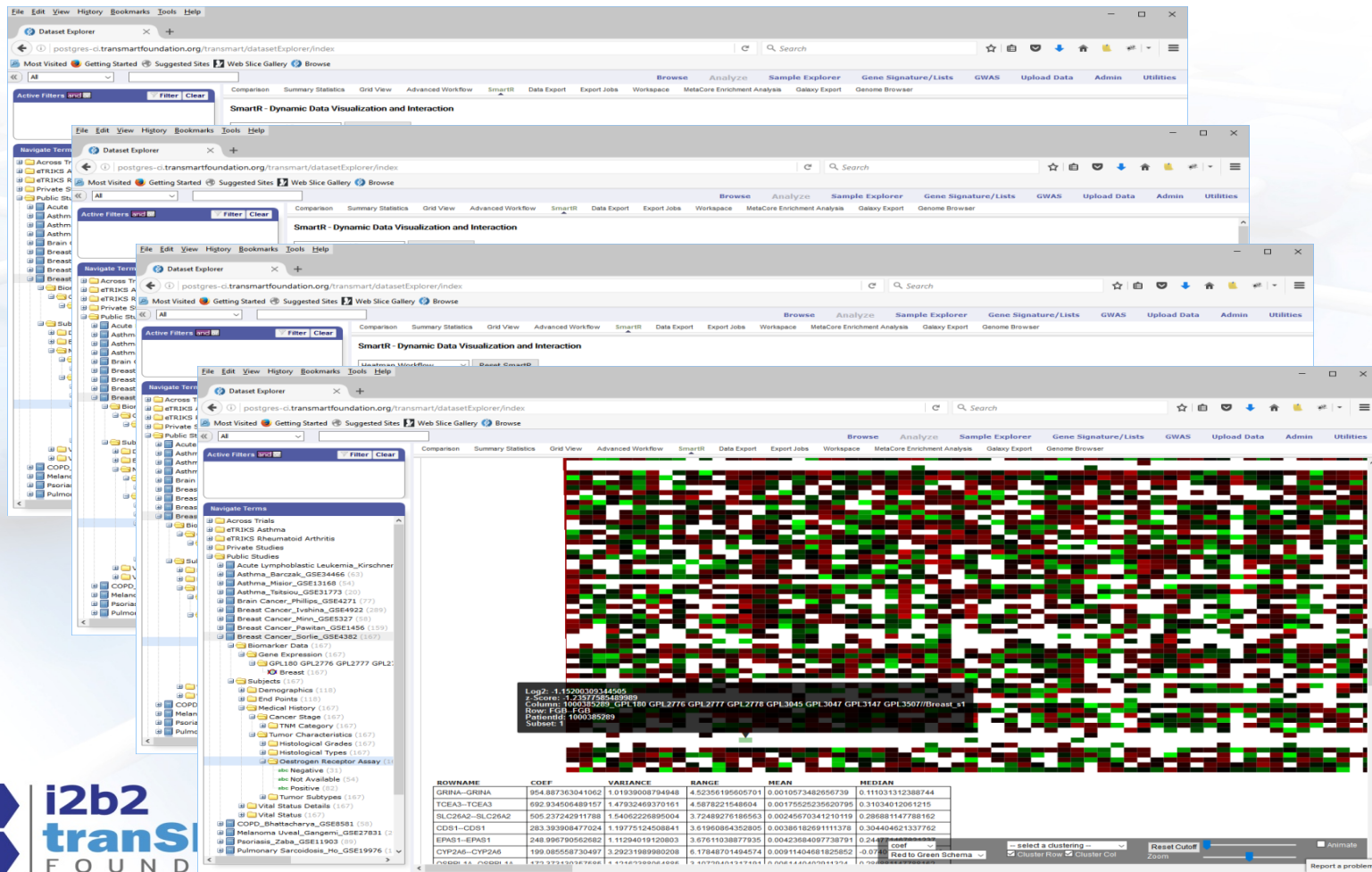
tranSMART's Role in Precision Medicine

- What is tranSMART?

- An open-source, translational science data warehouse
- An advanced clinical analytics solution
- A platform for collaboration
- A platform for data sharing
- The dominant platform used in academia and industry for translational research



Interactive Analytics and Statistics



Genetic-based Cohort Selection

The screenshot displays a web-based interface for genetic cohort selection. At the top, there are navigation tabs: "Analyze", "Gene Signature/Lists", "Admin", and "Utilities". Below this, there are sub-tabs for "Comparison", "Summary Statistics", "Grid View", "Advanced Workflow", "Data Export", "Export Jobs", "Analysis Jobs", and "Workspace".

The interface is divided into two main sections: "Subset 1" and "Subset 2". Each subset has "Include" and "Exclude" buttons, and a "Clear Panel" button. Below these, there are summary statistics for each subset:

- Subset 1: UNKNOWN | 191 | 100.0 %
- Subset 2: UNKNOWN | 233 | 100.0 %

A data table is displayed at the bottom, with columns: Trial, Sex, Age, Race, and BRCA1 in WeTRIKS Studi... The table contains 15 rows of data, all with "TCGA_OVARIAN" in the Trial column and "NULL" in the Sex, Age, and Race columns.

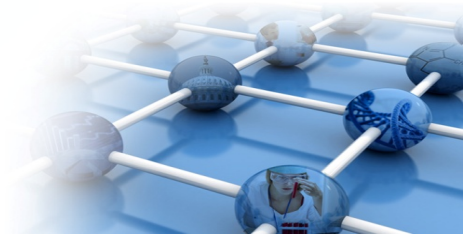
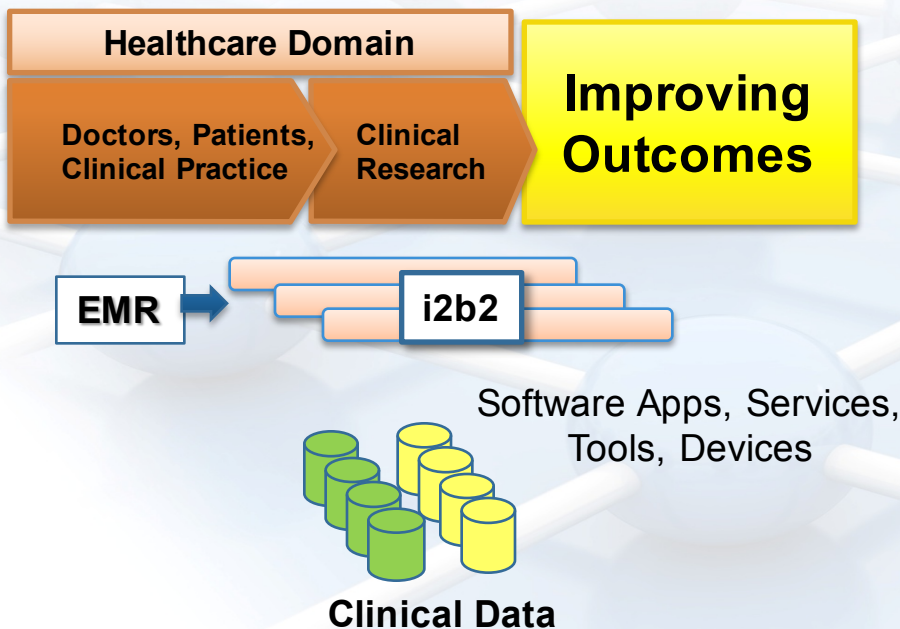
Trial	Sex	Age	Race	BRCA1 in WeTRIKS Studi...
TCGA_OVARIAN	NULL	NULL	NULL	-0.05
TCGA_OVARIAN	NULL	NULL	NULL	0.16
TCGA_OVARIAN	NULL	NULL	NULL	-0.16
TCGA_OVARIAN	NULL	NULL	NULL	0.44
TCGA_OVARIAN	NULL	NULL	NULL	0.36
TCGA_OVARIAN	NULL	NULL	NULL	0.28
TCGA_OVARIAN	NULL	NULL	NULL	0.28
TCGA_OVARIAN	NULL	NULL	NULL	-0.8
TCGA_OVARIAN	NULL	NULL	NULL	1.04
TCGA_OVARIAN	NULL	NULL	NULL	-1.05
TCGA_OVARIAN	NULL	NULL	NULL	0.36
TCGA_OVARIAN	NULL	NULL	NULL	1.16
TCGA_OVARIAN	NULL	NULL	NULL	1.2
TCGA_OVARIAN	NULL	NULL	NULL	-0.4
TCGA_OVARIAN	NULL	NULL	NULL	0.18
TCGA_OVARIAN	NULL	NULL	NULL	-0.14
TCGA_OVARIAN	NULL	NULL	NULL	0.05
TCGA_OVARIAN	NULL	NULL	NULL	0.28



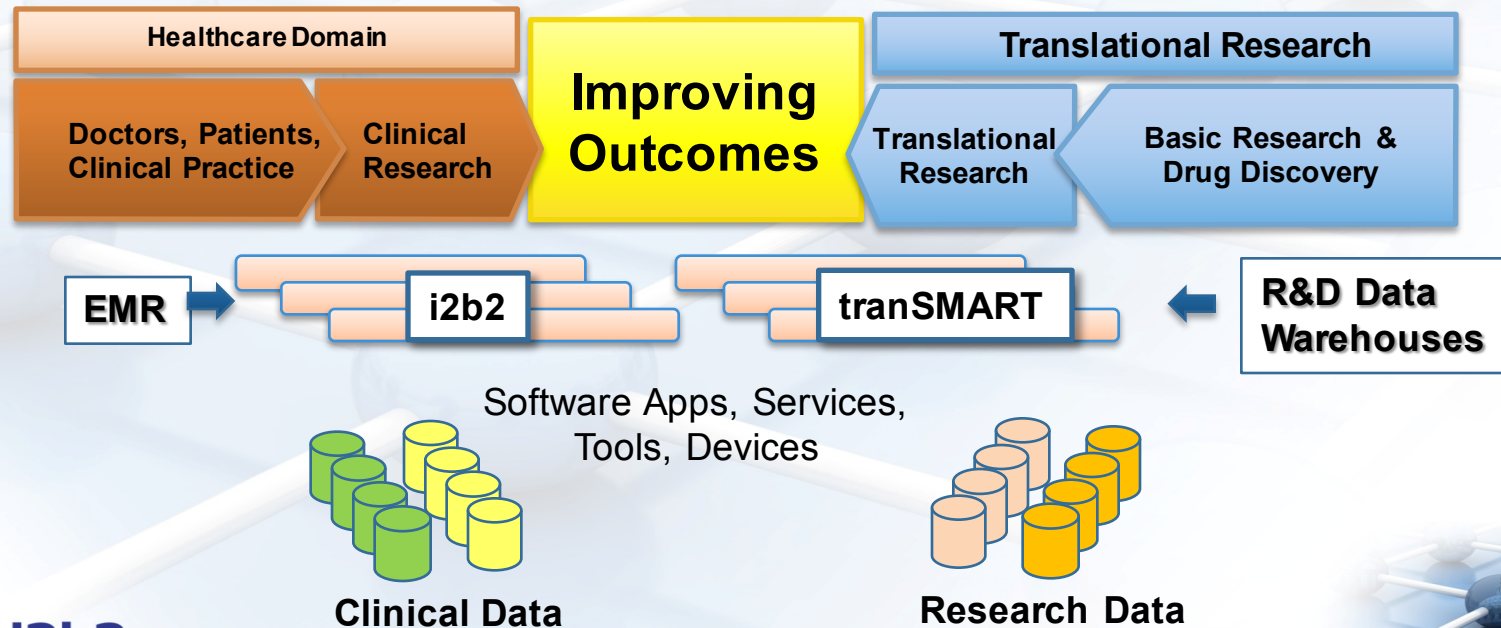
I2b2's Role in Precision Medicine

- What is i2b2?

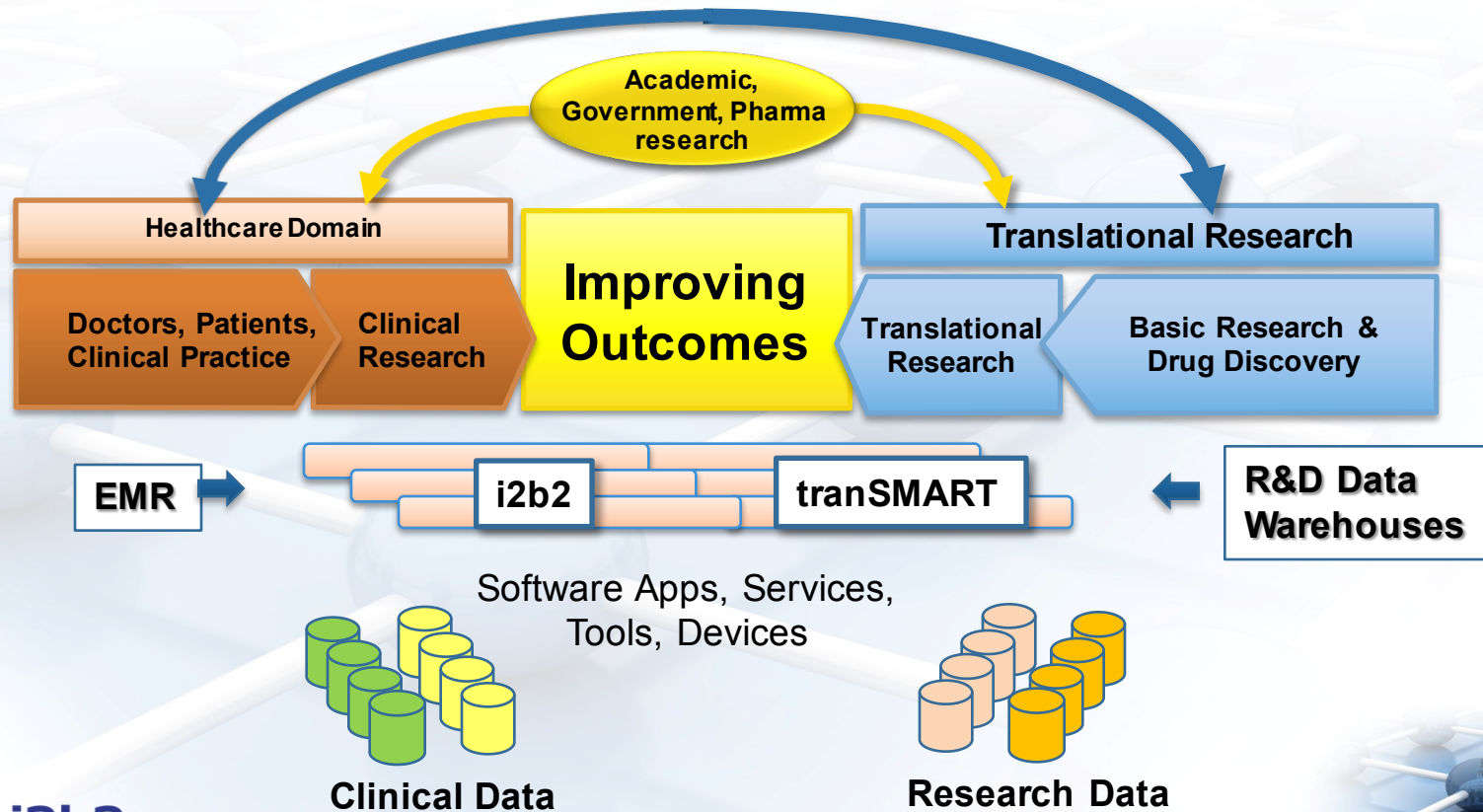
- An open source clinical research data warehouse
- An analytical platform for building phenotypic patient cohorts
- A platform with more than 250M patients data
- The dominant clinical research analytics platform in use by over 200 hospitals, medical centers and providers



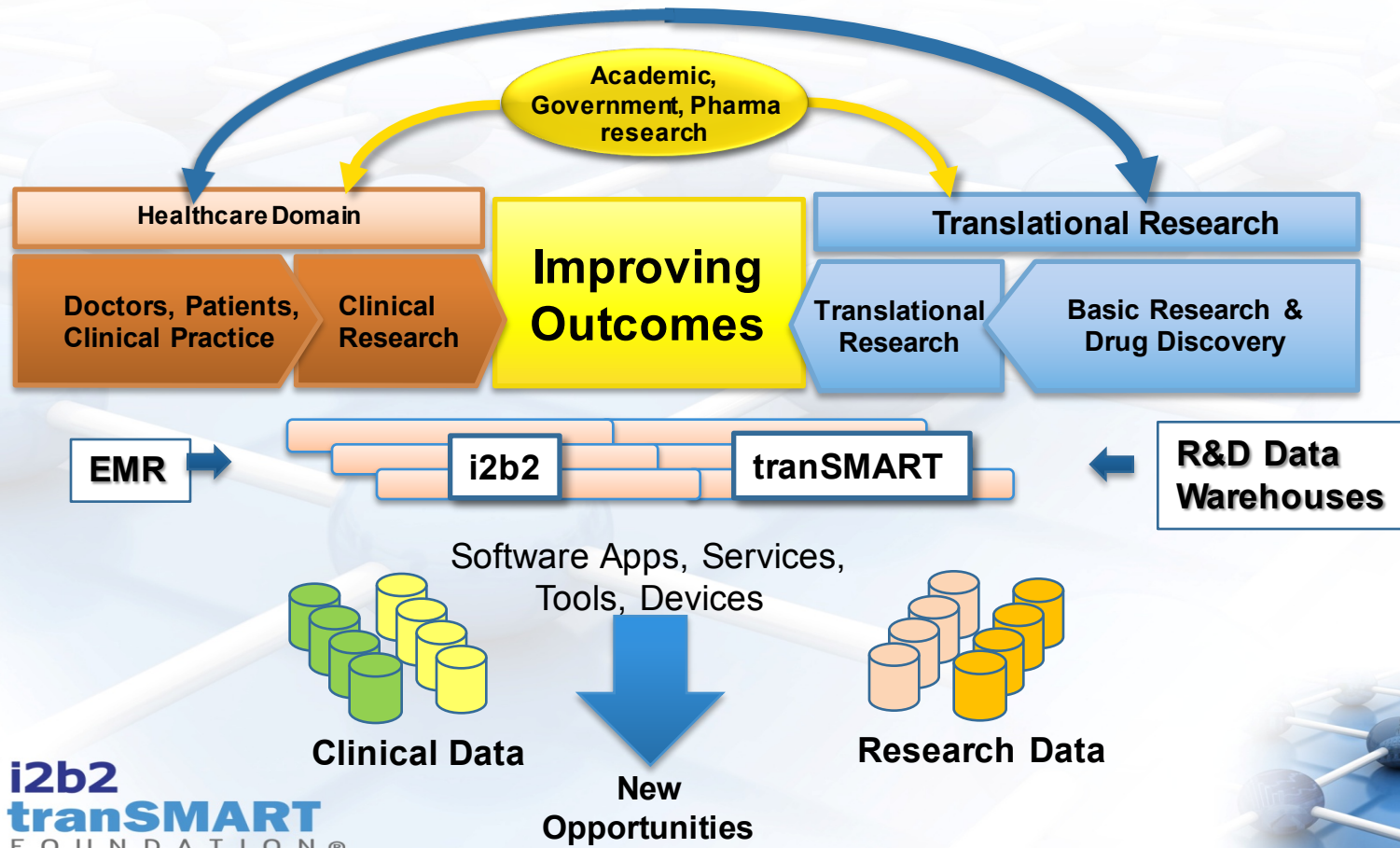
Bringing i2b2 and tranSMART Together



Bringing i2b2 and tranSMART Together

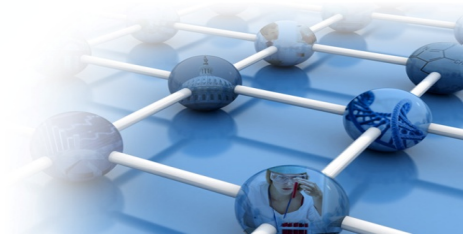


Bringing i2b2 and tranSMART Together



The i2b2 tranSMART Foundation

- **Vision:**
 - Realising the promise of precision medicine.
- **Mission:**
 - The i2b2/tranSMART Foundation enables effective collaboration for precision medicine, through the sharing, integration, standardization and analysis of heterogenous data from healthcare and research; through engagement and mobilization of a life sciences focused open-source, open-data community.

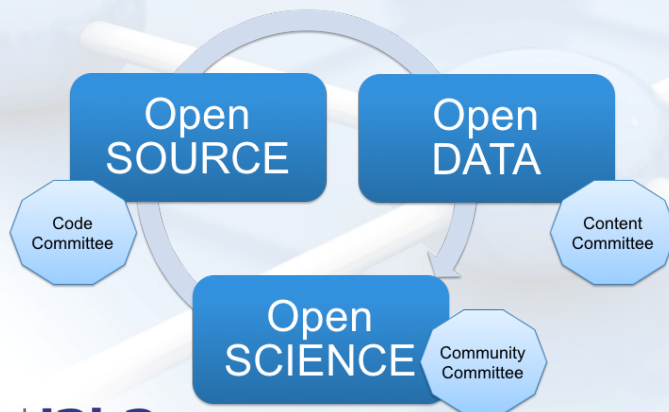


The i2b2/tranSMART Foundation

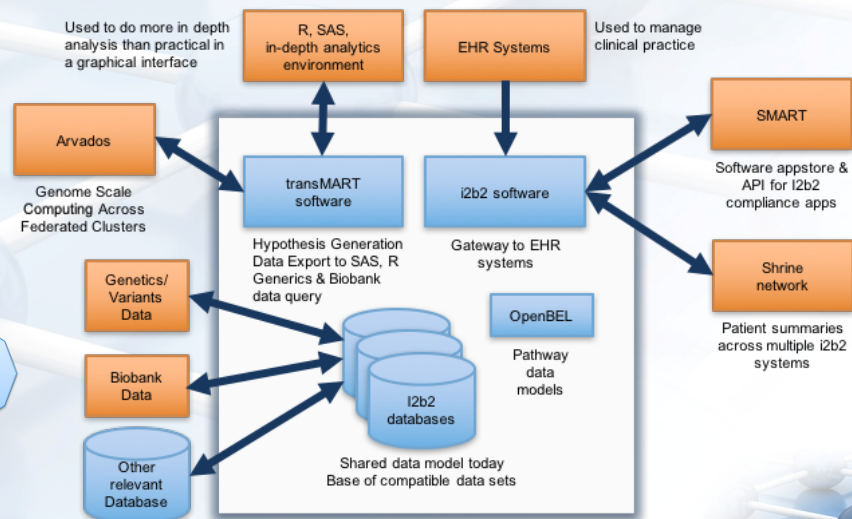
The Mission



The Community

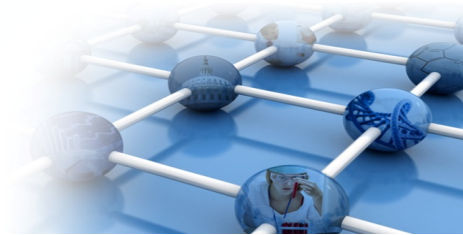


The Platform



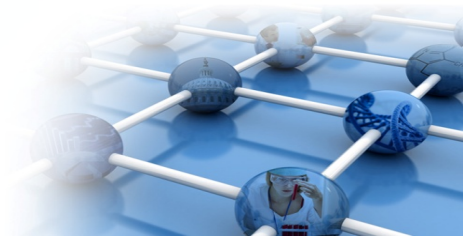
The i2b2/tranSMART Foundation – What we do

- **Manages Code Governance**
 - Maintains/Governs the tranSMART Codebase
 - Maintains/Governs the i2b2 Codebase
 - Develops a unified i2b2/tranSMART Codebase
 - Develops new open source projects that fit the Foundation mission
- **Develops a unified Precision Medicine / Learning Healthcare Community**
 - Academia, Industry, Pharma, Biotech, Hospitals, Healthcare, Gov't, Patients, Patient Advocacy Groups
- **Collects and Distributes Open Data**
 - Analysis ready data sets
- **Attracts new resources to contribute to the platform(s)**
 - In kind contributions, grants, philanthropy, etc.
- **Brings the community together for events**
 - Meetings, conferences, etc.
- **Provides a marketing capability for the platform**
 - Grow the user community and base



Goals

1. Establish and sustain the Foundation Software Products as the preferred data sharing and analytics platforms for research in precision medicine.
2. Link academic, non-profit, healthcare and commercial research communities for collaborative research in precision medicine, facilitated by the Foundation's platforms, products and initiatives.
3. Align and grow a vibrant developer network around the scientific goals of the i2b2/tranSMART Foundation community.
4. Reduce barriers to entry through use of advanced technologies, open-data and an active marketplace.



Our Goal (the Why)

- Create the best-in-class, open-source ecosystem
 - For learning healthcare systems AND precision medicine
- Build a critical mass
 - A community that spans hospitals, biomedical research, and treatment providers
 - # data sets
 - # institutions and users
 - # vendors supporting platform
 - Funding and support



Synergies and Benefits


- tranSMART Foundation non-profit status enables revenue growth from multiple funding models
- Strong academic history of i2b2 and the new i2b2 Foundation
- Eliminate duplication of capabilities to deliver a full precision medicine or learning healthcare system environment
- Both foundations are building on the same i2b2 data model and have complementary infrastructure
- Jointly encourage the development of commercial services to support the i2b2-tranSMART platform
- i2b2 experience with AWS HIPAA compliance cloud implementation

 tranSMART v1.2
Advanced Analytical tools
Biobank Explorer
Variant Explorer

 **SHRINE**
Shared Health Research Information Network
Federated Advanced Cohort Selection

Advanced Cohort Selection
 i2b2

 Arvados™
Big Data Federation
Genome Scale Workflows
Scalable Computing

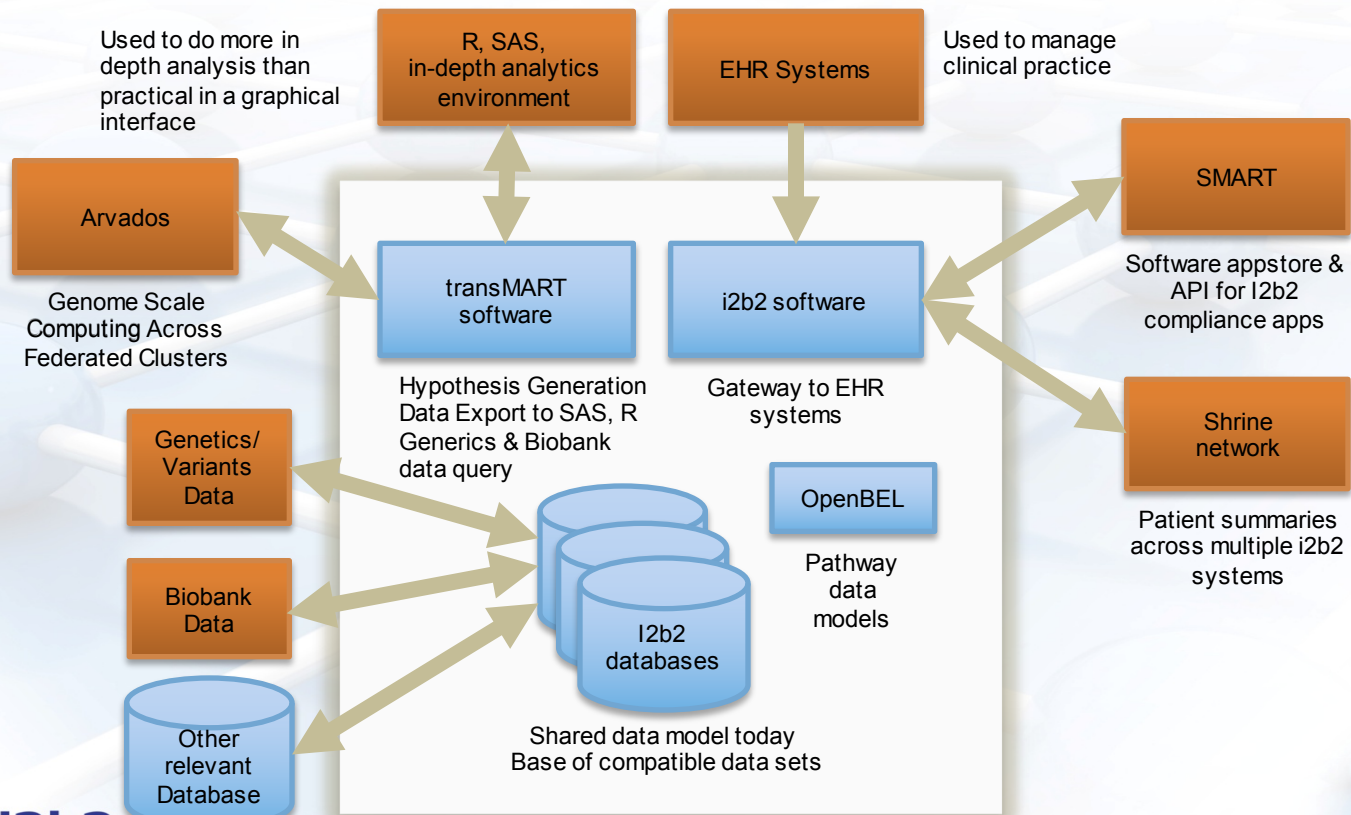
 FHIR®
 SMART®
Patient Level Data Lookup
Interoperable Tools



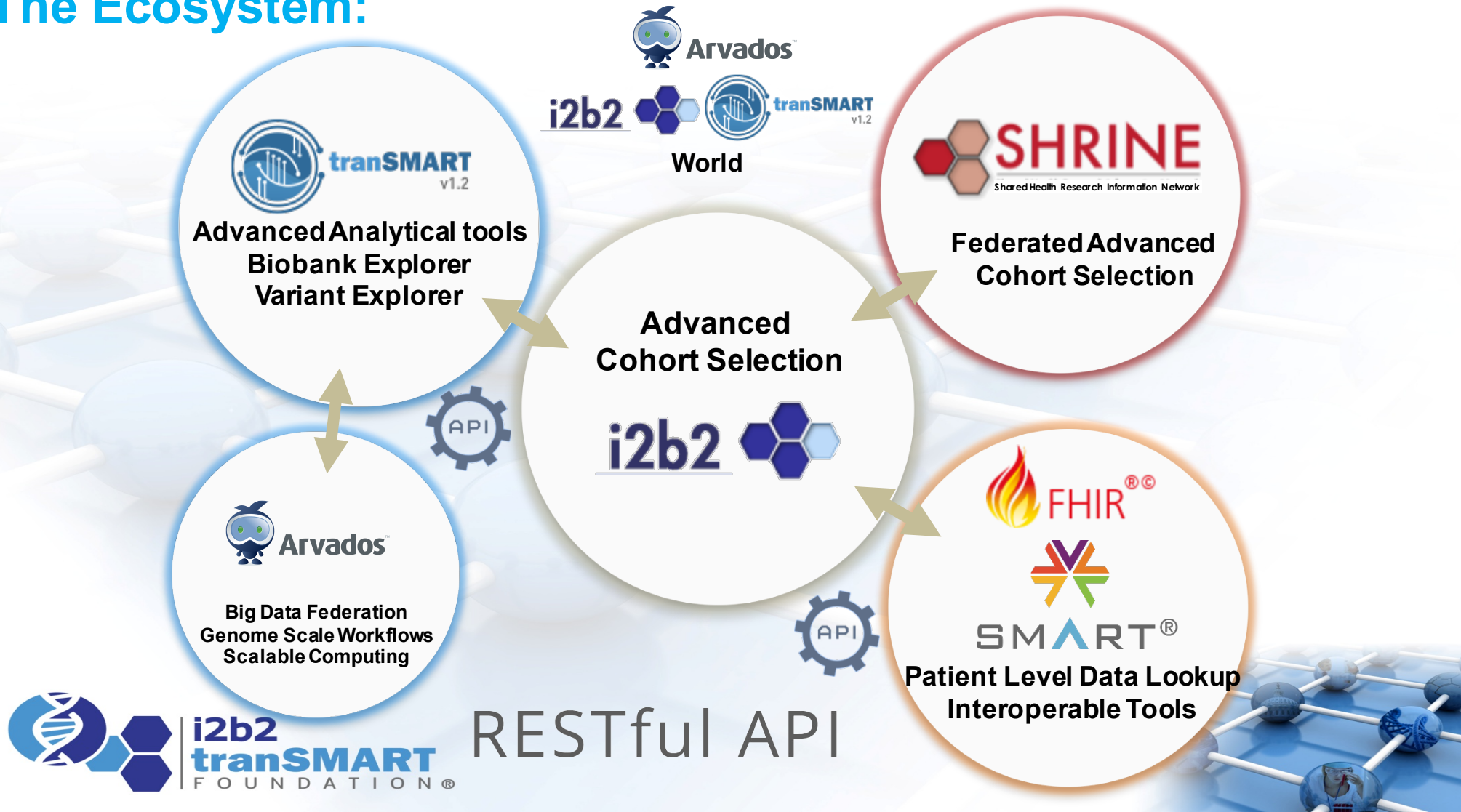
RESTful API



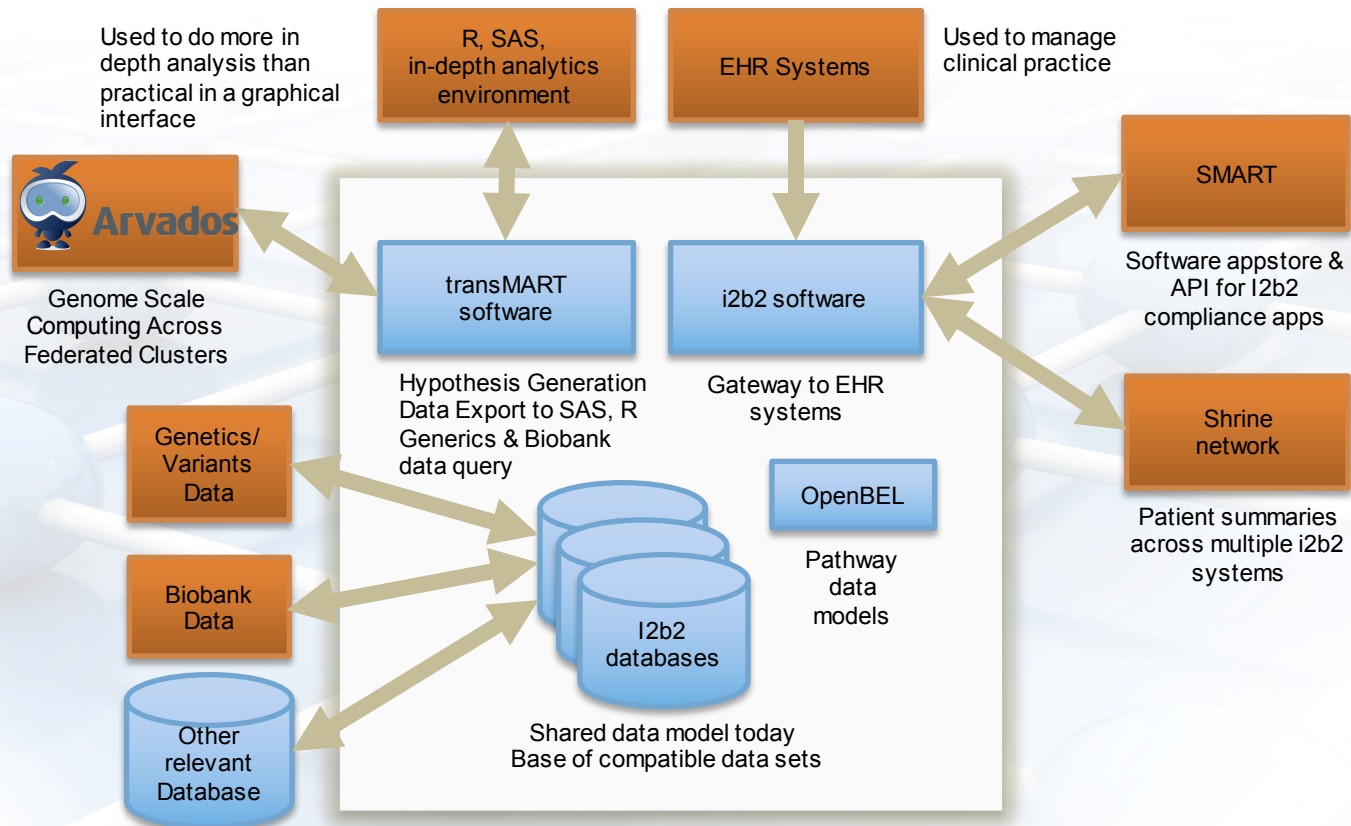
An integrated i2b2/tranSMART Ecosystem



The Ecosystem:



An integrated Precision Medicine Ecosystem



The most viable and sustainable business model is an open-source ecosystem

Projects Overview and History

- tranSMART
 - tranSMART PMC in place since 2015
 - 3 major releases and 4 minor releases since 2013
 - Currently have tranSMART 17.1 in the release process
- openBEL
 - Currently forming the PMC
 - Project plan in development
 - Currently being used by numerous projects in Europe and US
- I2b2
 - Currently at release 1.7, and forming a PMC
 - Ongoing development under various grant funding
 - Collaborative development with TriNetX
- I2b2/tranSMART
 - Prototype in use at Harvard
 - ~6 Grants for ~\$20M at DBMI using i2b2/tranSMART
 - Forming PMC to aid in productization and community development

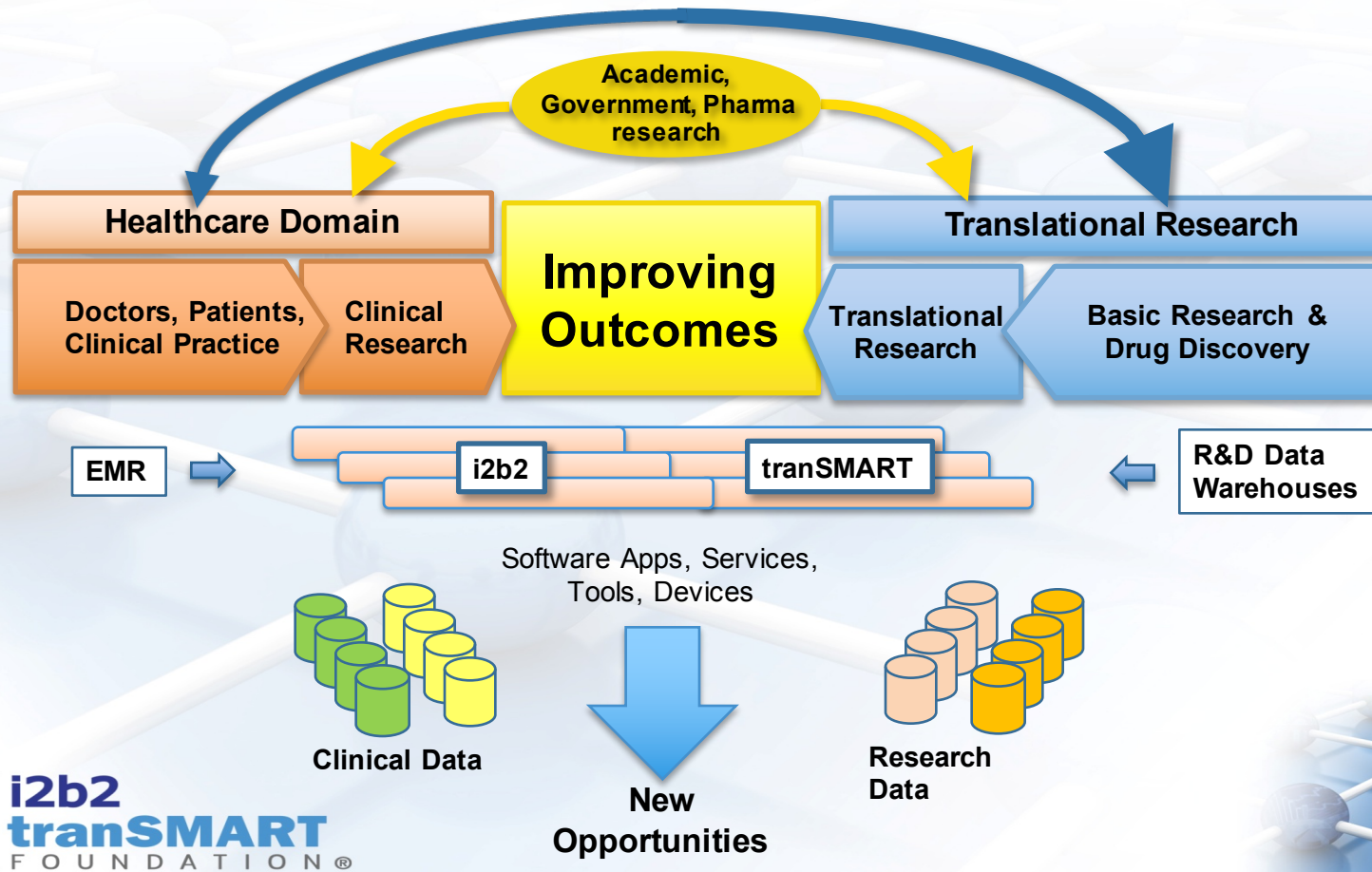


Benefits to the Community

- Builds Critical Mass in the community
- Provides a unified strategy for the platform and ecosystem
- Enables a single, seamless environment from patient care to research bench
- Unites two strong brands into a single identity (i2b2/tranSMART)
- Unites the long history and capability of i2b2 with corporate structure and infrastructure of the tranSMART Foundation
- Creates greater opportunities for collaboration, innovation and funding




I2b2/tranSMART and the Data to Knowledge Process



Governance Model



Business Advisory Board



Leadership Team



Partners Program

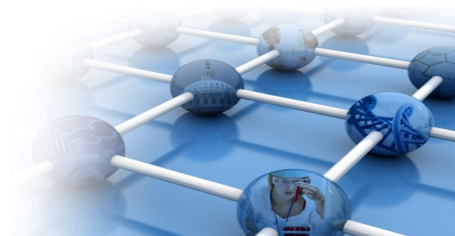


members



PMC
PROJECT MANAGEMENT
TIME COST PROCESS CONTROL PROJECTS DEVELOPMENT PLANNING

Project Management Committee



Governance Model

- Board of Directors
 - 11 Directors and 3 Committees
 - Directors drawn from i2b2 and tranSMART Foundation boards
 - 2 co-chairpersons
 - SAB Chairperson
- Members group
 - nominates and elects Board Members
 - Nominates and elects new members
- Executive Committee
 - 3 directors that will meet with the Executive Director on a monthly or more frequent basis
 - Will enable effective transaction of Foundation business between board meetings
- Governance Committee
 - Will oversee the membership elections, board nominations and board elections
 - Will provide oversight for bylaws and corporate policies
- Finance Audit Committee
 - Will work with management to develop and oversee budgets and spending
 - Will audit annual financial reports

Membership Model (follows ASF model)

- Foundation Members will include a merit-based group of stakeholders who will be engaged in Foundation operations, fundraising, software development and will elect new board members.
- This group will initially be ~50 members, drawn from key stakeholders and contributors to the foundations.
- Foundation Members will be elected for life, but can be made Emeritus Members based on contribution and activity in the Foundation.
- The members will meet once annually to be updated by the Board and management team on key activities of the Foundation, and where there will be an election of new members and board members.
- New members are nominated by existing members, and can be elected by the Foundation Members at their annual meeting. Membership will be based solely upon merit and contribution.



I2b2/tranSMART Foundation Board Directors

• i2b2 Foundation

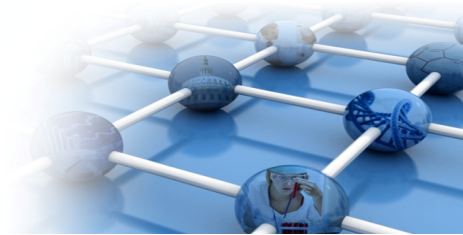
- Zak Kohane (co-Chair)
- Shawn Murphy
- Paul Avillach
- Russ Waitman

• tranSMART Foundation

- Gil Omenn (co-Chair)
- Matteo di Tommaso
- Brett Davis
- Jim Serum

Independent Directors

Christel Daniel (France)
Julie Bryant (USA)
Ulrich Sax (Germany)



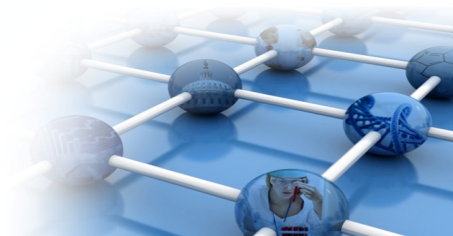
Leadership Team

• Operational Management:

- Executive Director
 - Keith Elliston
- VP Operations
 - Diane Keogh
- VP Finance
 - Steve Johnson
- VP Marketing
 - Rudy Potenzzone

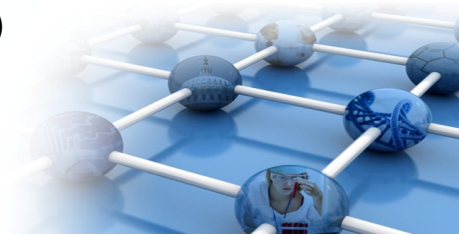
• Scientific Leadership:

- Chief Scientific Officer
 - Brian Athey
- Chief Medical Officer
 - Shawn Murphy
- Chief Technology Officer
 - Yike Guo
- Chief Information Officer
 - Paul Avillach



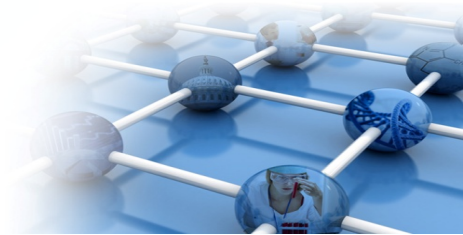
Project Management Committees

- What is a PMC?
 - A project management committee (PMC) is a committee of the i2b2/tranSMART Foundation charged with responsibility for governing a top level project.
 - The PMC is the vehicle through which decision making power and responsibility for oversight is devolved to developers.
 - The PMC also supports and manages the code governance set by the Executive management and Board of the Foundation
- PMC Governance
 - Merit-based group of developers and stakeholders contributing to the product
 - Members elect a chair, who is appointed as an officer of the Foundation
 - Chair reports directly to the board, and presents on a quarterly basis
 - All PMC positions are volunteer roles (as at Apache Software Foundation)



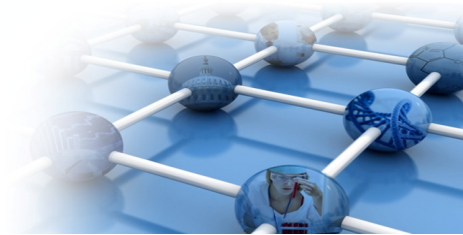
Role of the PMCs

- The primary role is governance and oversight of the software product or platform it is charged with responsibility for
 - meeting its goals
 - is on budget (to the extent that Foundation managed resources are being used)
 - is of acceptable quality according to Foundation standards, complies with the coding standards and code governance guidelines set forth by the Foundation
 - meets all legal, ethical, moral codes of the Foundation
 - Supported by the VP of Operations and management team
- Secondly the role of the PMC is
 - To further the long term development and health of the community as a whole
 - To ensure that broad and balanced peer review and collaboration is enabled



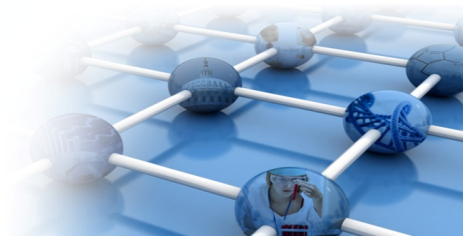
Partnership Program

- Modification and key enhancements to the previous Membership Program for tranSMART Foundation
- Multiple Partnership levels with increasing benefits to provide opportunities for more participation with increasing sponsorship
- Provides a means for improving collaboration between Partners and the Foundation
- Opens channels to the extended i2b2/tranSMART Foundation Community through the Marketplace
- Partners gain discounted access to the sponsorship program for Foundation events, advertising and social media



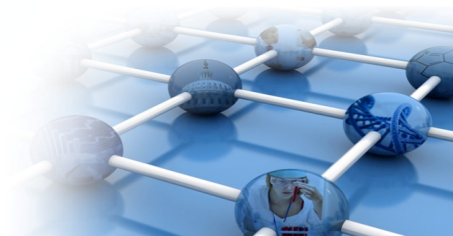
Benefits of Foundation Partnership

- **Board and Management**
 - Gain direct access to the Foundation executives and the growing scientific Community
- **Business Advisory Board**
 - Biannual meetings to discuss critical issues with board members, PMC chairs and management
- **Foundation Events**
 - Annual meeting passes, attend invitation-only events, hackathon and datathon participation.
- **Marketing**
 - Membership in the Marketplace, discounts on event sponsorships and advertising, prominent placement of organizations brand on Foundation social networks, web properties and monthly events, use of Foundation trademarks
- **Foundation Projects**
 - Propose new projects, govern projects, sponsor projects



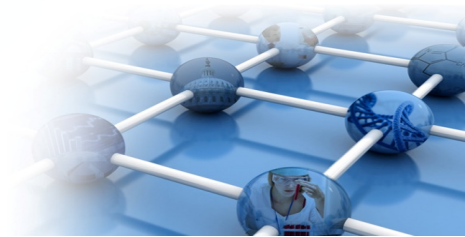
Partnership Program Levels

Benefits		Platinum Partner	Gold Partner	Silver Partner	Academic Affiliate
Board of Directors	BOD Dinner	YES	YES		
	BOD Presentation	YES			
Business Advisory Board	Advisory Board Seat	YES	YES		
	Advisory Board Presentation	YES			
Foundation	3C Committees	All 3	Any 2	Any 1	
	Annual Meeting Passes	6	3	2	3
	Foundation Trademarks	YES	YES	YES	
Marketing	Event Sponsorship	50% off	30% off	20% off	-
	Marketplace Advertising	YES	YES	YES	
	Advertising	50% off	30% off	20% off	-
Projects	Propose New Projects	YES	YES		
	Govern New Projects	YES			
	Sponsor New Projects	YES	YES	YES	



The Partnership Program Cost

Company Size	Platinum Partner	Gold Partner	Silver Partner
>3000	\$100,000	\$50,000	\$25,000
101 - 3000	\$50,000	\$25,000	\$15,000
100 or less	\$25,000	\$15,000	\$5,000
Academic Partner	\$15,000	\$5,000	\$2,000
Academic Affiliate	N/A	N/A	\$0



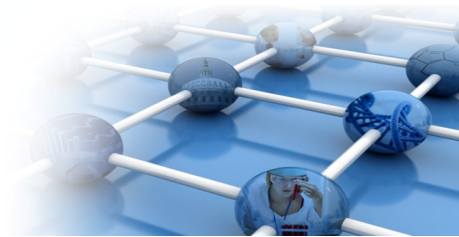
Summary

- New, integrated open-source infrastructure for Precision Medicine
 - Unites i2b2 and tranSMART Platforms
 - Opportunities for growth and expansion
 - E.g., Arvados integration
- New, integrated open-source Foundation
 - I2b2/tranSMART Foundation
 - Continues the traditions of i2b2 and tranSMART
 - Creates new opportunities and improves critical mass
- Precision Medicine in the Cloud is Real
 - I2b2/tranSMART runs securely in AWS
- The future is in expanding the open-source toolkit for precision medicine



TRANSMART PMC

Peter Rice
i2b2 tranSMART Foundation



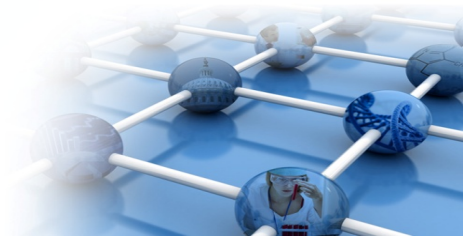
tranSMART PMC Current Members

- Rudy Potenzzone (Chair) – i2b2 tranSMART
- Diane Keogh - i2b2 tranSMART
- Peter Rice - i2b2 tranSMART
- Alex Papa – Pfizer
- Christophe Trefois (ITTM)
- Denny Verbeek – J&J
- Gayle Wittenberg – J&J
- Sascha Herzinger – U Lux
- Marishka Bierkens - NKI
- Ward Weistra – the Hyve
- Tania Khasanoa – Rancho
- Yulia Skovpen – Rancho
- Julia Kozlovsky – Clarivate
- Stephen Wicks – Clarivate
- Sirimon O'Charoen – Crohn's & Colitis Foundation
- Chris Marshall – metaseq

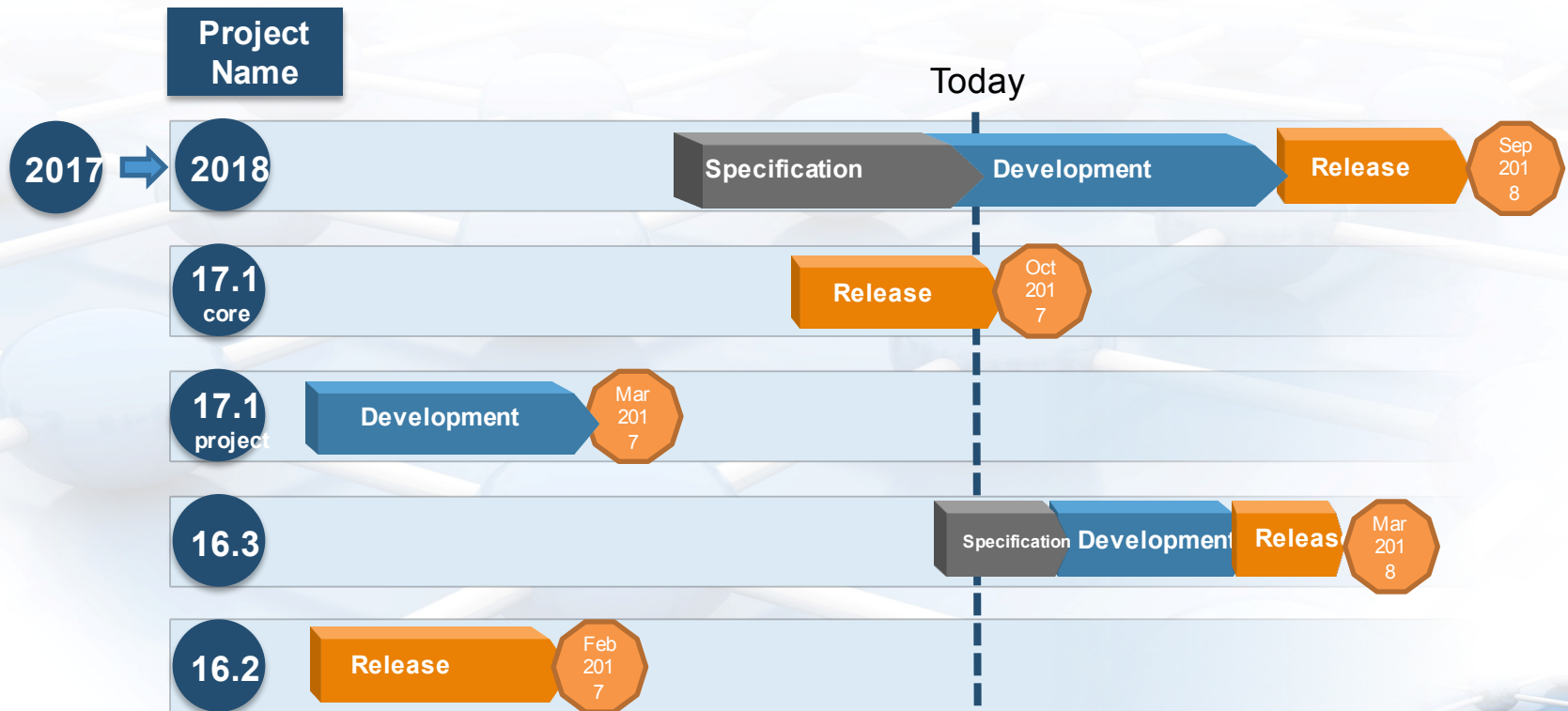


Roadmap for the tranSMART Platform

- Schedule release of tranSMART 2018 that includes:
 - 17.1 project enhancements
 - New architectural elements
 - One or more new GUI(s)
 - Automated testing
 - New ETL tool(s) – hopefully only 1 or 2 but fully tested and optimized
 - Next gen SmartR; etc.
 - I2b2 data model integration
 - Improved data access through API
 - Most likely late summer or fall release
- i2b2 tranSMART PMC proceeds with tranSMART 16.2 code base
- Add a 16.3 Release for early 2018

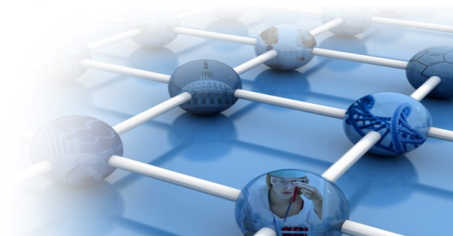


Current Roadmap – Sep 2017



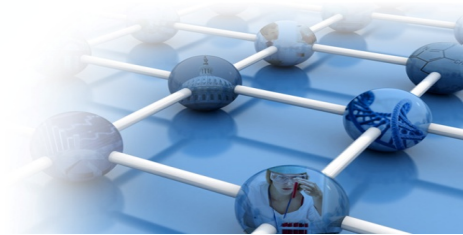
I2B2 PMC ROADMAP

Shawn Murphy, MD PhD
Partners Healthcare



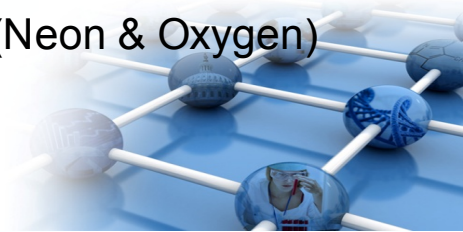
I2b2 PMC Current Members

- Janice Donahoe Partners Healthcare
- Shawn Murphy (Chair) Partners Healthcare
- Mike Mendes Partners Healthcare
- Diane Keogh i2b2/tranSMART foundation
- Lori Philips Partners Healthcare
- Nich Wattanasin Partners Healthcare
- Chris Herrick Partners Healthcare
- Bhaswati Ghosh Partners Healthcare



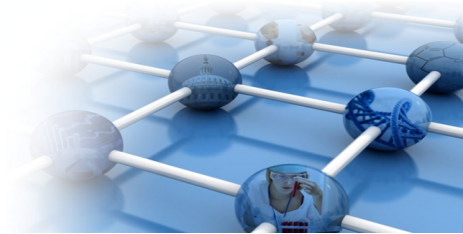
i2b2 PMC Roadmap – Workbench enhancements

- New Linux VMs
 - 2 new VMs using VirtualBox
- Timeline Changes – new features
 - Two types of Popups
 - New ‘starred’ and ‘already-read’ markings
 - Note Viewer improvements
- Temporal Query Tool Changes
 - User interface for creating and executing temporal query from i2b2 Workbench
 - Changes to accommodate Linux
- I2b2 Workbench: Eclipse & Plugin Changes
 - Updated i2b2 workbench to compile and run the latest version of Eclipse (Neon & Oxygen)



i2b2 PMC Roadmap – Genomic Release

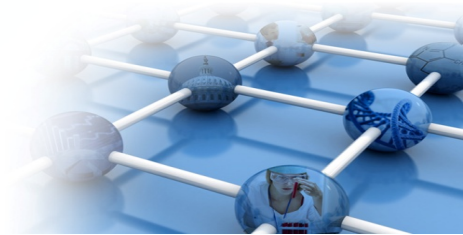
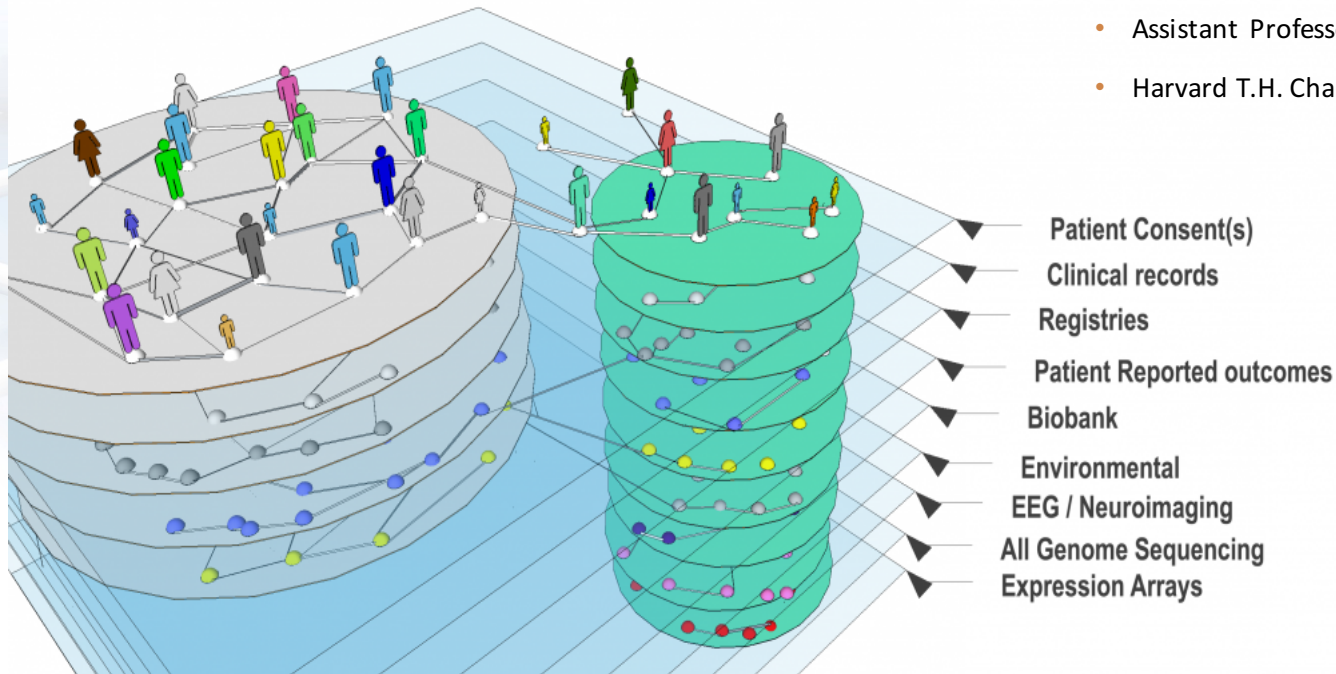
- i2b2-Genomic data is a combination of Ontology data, Patient data and auto-completed data
- Genomic Ontology presents the genetic variant as a query-able concept in the i2b2 web-client
- Demo Genomics Patient Data



i2b2/tranSMART PMC Roadmap

- **Paul Avillach, MD, PhD**

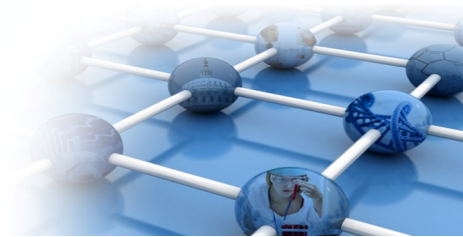
- Assistant Professor of Biomedical Informatics and Pediatrics
- Harvard Medical School - Boston Children's Hospital
- Assistant Professor of Epidemiology
- Harvard T.H. Chan School of Public Health



I2b2 tranSMART Current PMC Members

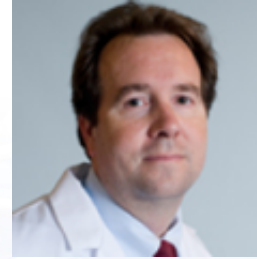
- Adem Albayrak Dana Farber cancer institute
- Paul Avillach (Chair) Harvard Medical School
- Melanie Davies Dana Farber cancer institute
- Diane Keogh i2b2/tranSMART foundation
- Ranjay Kumar Harvard Medical School
- Andreas Kremer Information Technology for Translational Medicine
- Jomol Mathew University of Massachusetts Medical School
- Rudy Potenzzone i2b2/tranSMART foundation
- Peter Rice i2b2/tranSMART foundation
- Jason Stedman Harvard Medical School
- Venkata Satagopam Université du Luxembourg
- Ward Weistra The Hyve







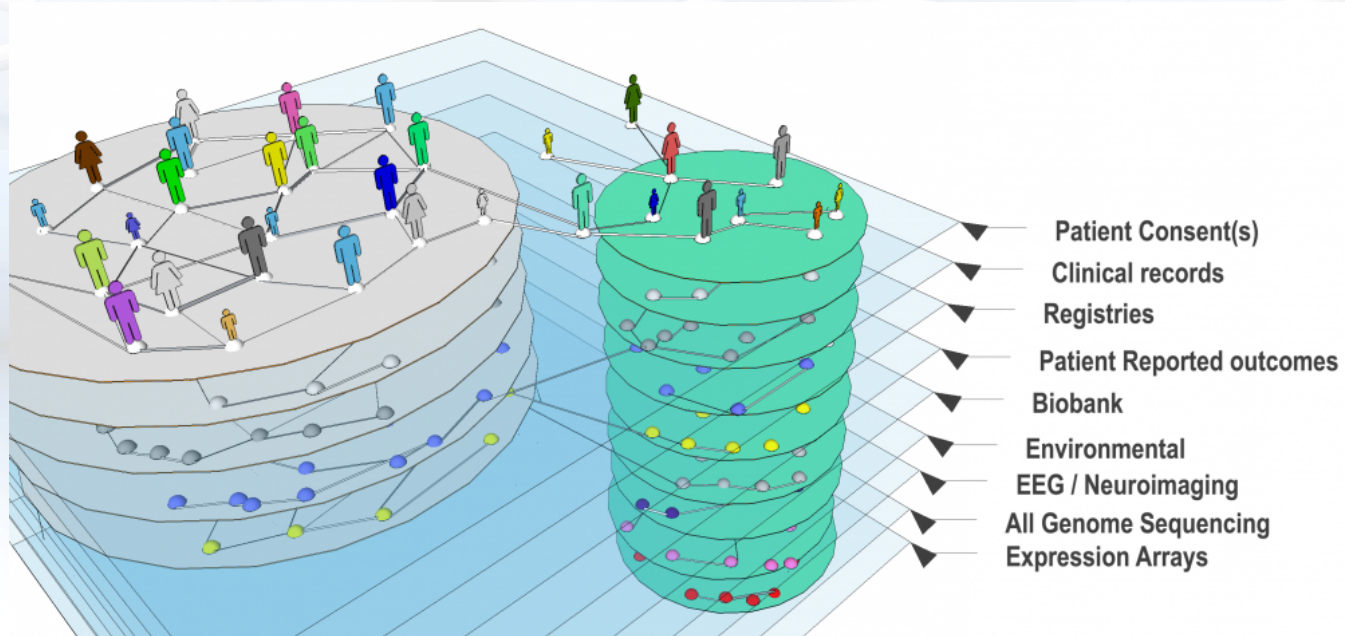
Isaac Kohane

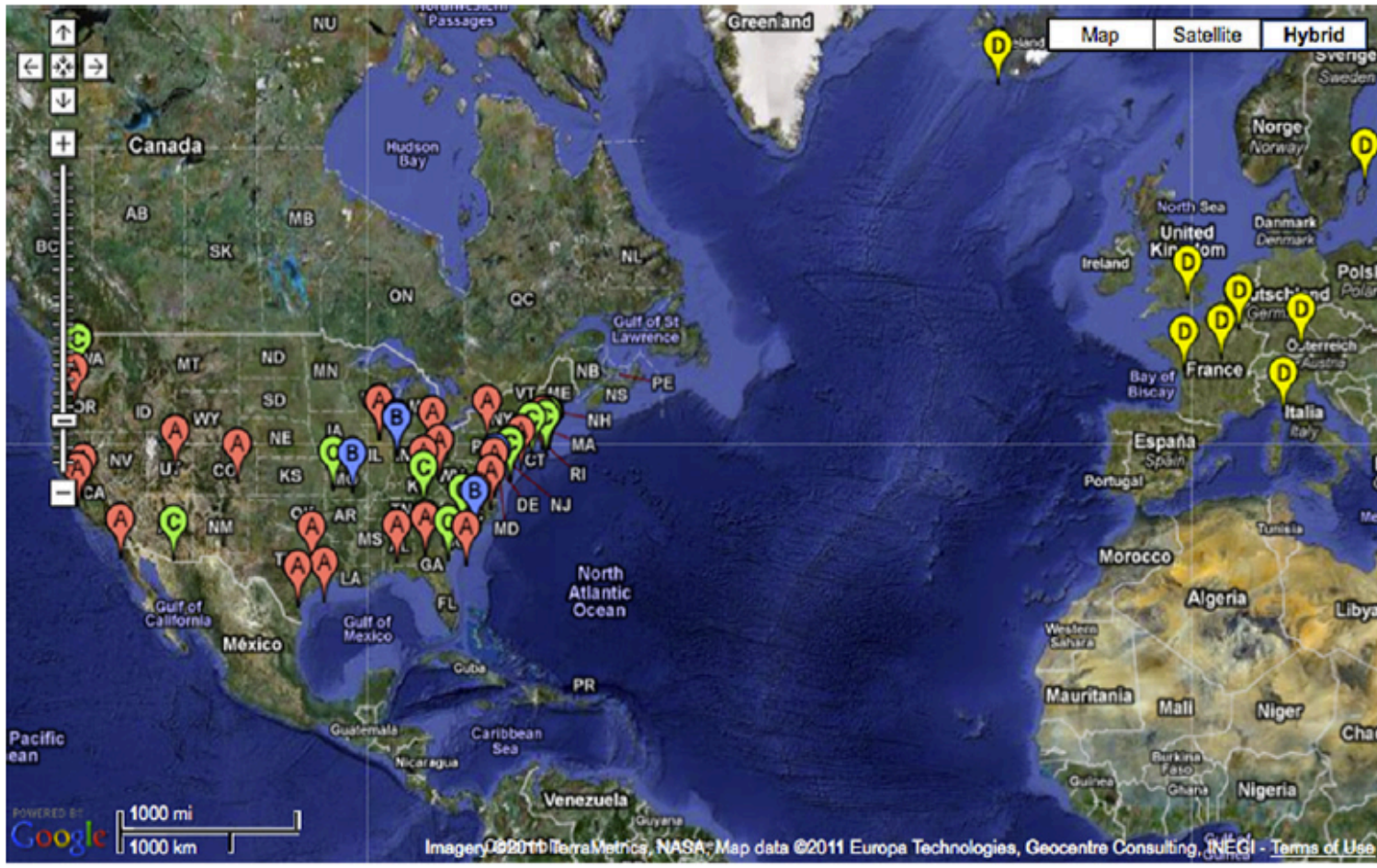


Shawn Murphy



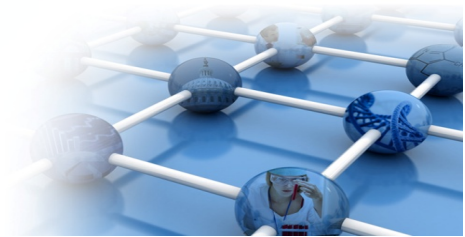
Susanne Churchill





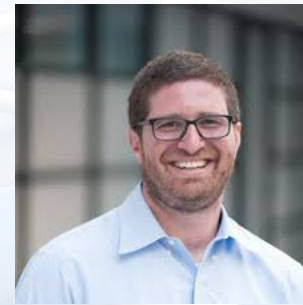


transSMART





Eric Perakslis



Dan Housman

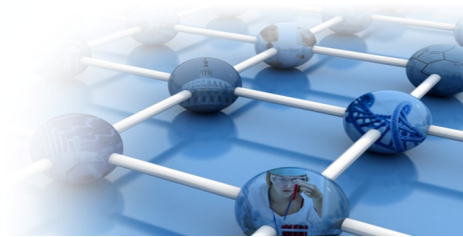




Open source since Jan 24th 2012

v0.9

v1.0 HOTFIX





European Translational Information and Knowledge Management Services

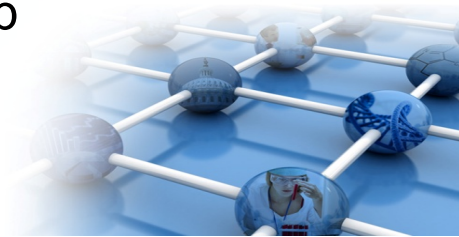


tranSMART

v1.1



I2b2 database still there
But NOT i2b2 jboss app

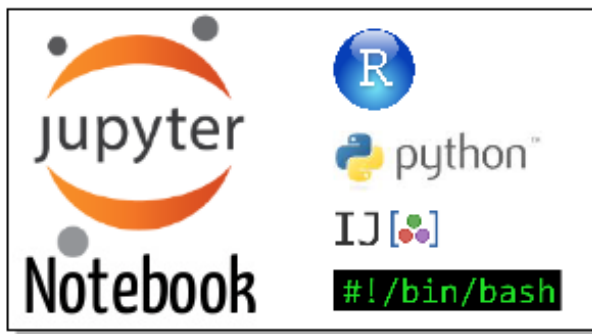




Open Source Research Infrastructure



Google Cloud Platform



transSMART
FOUNDATION®

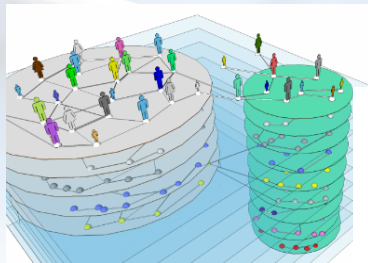


1.0_HOTFIX



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Biomedical Informatics



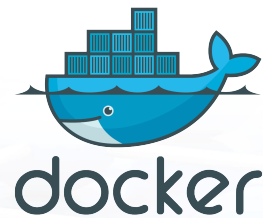
Harvard – DBMI
Avillach Lab
improvements



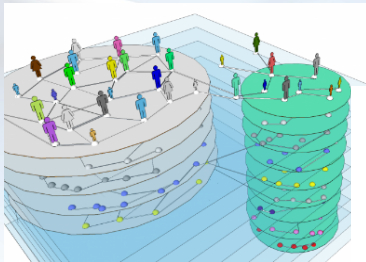
HARVARD
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Biomedical Informatics





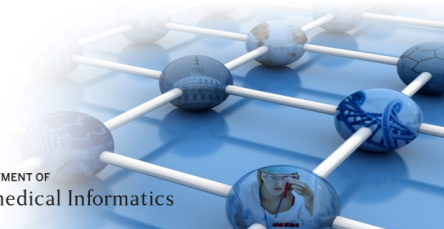
16.2 (~~17.1?~~)



Harvard – DBMI
Avillach Lab
improvements

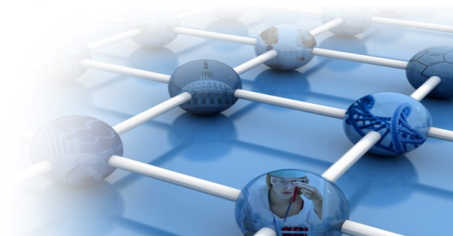


DEPARTMENT OF
Biomedical Informatics



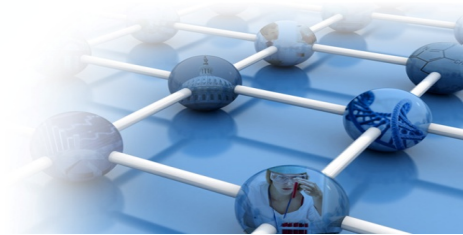
Early draft roadmap i2b2/tranSMART PMC

- **Dockerization survey** <http://tinyurl.com/docker-i2b2-tm>
 - List and Evaluate tranSMART 16.2 Dockerfiles
 - How many implementations?
 - How uses them in production?
 - List and Evaluate I2b2 1.7 Dockerfiles
 - How many implementations?
 - How uses them in production?
- **Establish (RFC) Request For Comments open standards**
- **Deploy a development server on AWS with Docker (including database) of both : i2b2 1.7 and tranSMART 16.2**
- **Authentication**
- **Authorization**



I2b2 tranSMART Current PMC Members

- Adem Albayrak
Dana Farber cancer institute
- Paul Avillach (Chair)
Harvard Medical School
- Melanie Davies
Dana Farber cancer institute
- Diane Keogh
i2b2/tranSMART foundation
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- Jason Stedman
Harvard Medical School
- Venkata Satagopam
Université du Luxembourg
- Ward Weistra
The Hyve



**i2b2/tranSMART
project management committee**

If interested to join, email us:

Diane:

dkeogh@i2b2foundation.org

paul_avillach@hms.harvard.edu





Questions?