tranSMART: An Open Source and Community-Driven Informatics and Data Sharing Platform for Clinical and Translational Research

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Abstract

tranSMART is an emerging global open source public private partnership community developing a comprehensive informatics-based analysis and data-sharing cloud platform for clinical and translational research. The tranSMART consortium includes pharmaceutical and other companies, not-for-profits, academic entities, patient advocacy groups, and government stakeholders. The tranSMART value proposition relies on the concept that the global community of users, developers, and stakeholders are the best source of innovation for applications and for useful data. Continued development and use of the tranSMART platform will create a means to enable "pre-competitive" data sharing broadly, saving money and, potentially accelerating research translation to cures. Significant transformative effects of tranSMART includes 1) allowing for all its user community to benefit from experts globally, 2) capturing the best of innovation in analytic tools, 3) a growing 'big data' resource, 4) convergent standards, and 5) new informatics-enabled translational science in the pharma, academic, and not-for-profit sectors.

General Description

Building the Global Community

The Pistoia Alliance (Pistoia), Imperial College London (ICL), and the University of Michigan (U-M) are leading community building activities that bring together and align European Union (EU; funded via ETRIKS) and US-based (proposed) resources to achieve the tranSMART vision. These activities include convening pharmaceutical, diagnostic and other companies with US-based academics and government to 1) set scientific, data, analytics, and platform priorities; 2) secure long-term sustainable funding via

a diversity of sources; and 3) coordinate with European Union initiatives through lightweight, transparent governance including promotion and outreach.
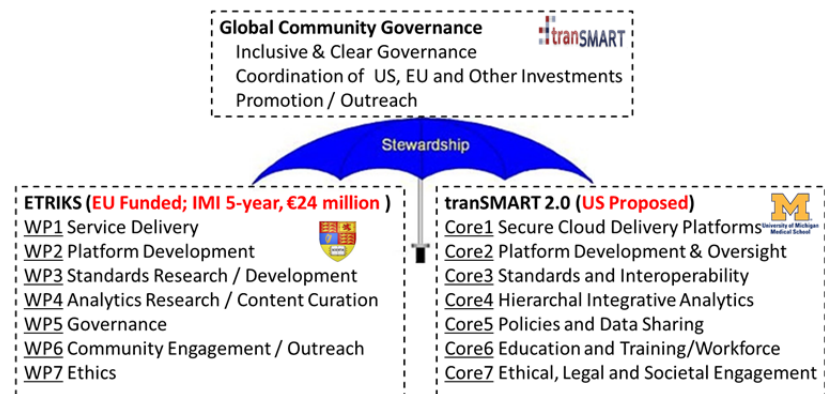
Organizations Adopting or Evaluating tranSMART include

- *Pharmaceutical Companies*: Johnson & Johnson, AstraZeneca, Sanofi, Roche, Millenium, GlaxoSmithKline, Bayer, Merck, Pfizer, Eli Lilly, Bristol-Myers Squibb, AssureRx Health

- *Not-For-Profits and Patient Advocacy Groups*: Institute for Systems Biology (ISB), One Mind for Research, Multiple Myeloma Research Foundation (MMRF), Juvenile Diabetes Research Foundation (JDRF), National Network of Depression Centers, Sage Bionetworks, CHDI Foundation, Open Health Tools

- *Academics*: University of Michigan, Harvard University, Boston Children's Hospital, Dana-Farber Cancer Institute, Carnegie Mellon University, Imperial College London, University of Luxembourg Centre for Systems Biomedicine

- *Government*: National Institutes of Health (NIH), Food and Drug Administration (FDA), European Union

- *Value-added Service Providers*: Recombinant Data Corp, 5AM Solutions, Akira Technologies, IDBS, Kitware Inc.

tranSMART Early Adopters

Johnson & Johnson (JnJ) is the creator of tranSMART. Janssen R&D, Inc., a JnJ company, has placed tranSMART into the open source and has funded nascent activities including community and technical infrastructure support and ongoing development of the tranSMART platform, code management/certification, and promotion/outreach. Janssen participates in the EU ETRIKS project.

Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines. IMI has funded the 5-year €24 million ETRIKS project to build a knowledge management platform using tranSMART as its foundation with Imperial College London as academic lead. The project includes 10 pharmaceutical and 6 academic organizations. The project aims to create a cloud-based knowledge management platform for all IMI translational research projects where tranSMART will be further developed as a collaborative research support environment for PPP-based translational studies.

University of Michigan (U-M) has deployed tranSMART to support the U19 NIH-funded post-GWAS ColoRectal Transdisciplinary Study (CORECT). Additional deployments are planned for diabetes and renal testbeds. The U-M based NIH National Center for Integrative Biomedical Informatics (NCIBI) is integrating its analytical tools, data and web services to provide enhanced capabilities for tranSMART.

One Mind for Research's 5-year vision for creating a Knowledge Integration Network (KIN) that initially focuses on traumatic brain injury (TBI) and post-traumatic stress disorder (PTSD) is building upon existing tranSMART capabilities. Phase 1 activities include integration of Synapse (Sage Bionetworks) with tranSMART.

Organizing and Funding the tranSMART Ecosystem

Nascent open source collaborative activities have been funded by Janssen R&D, Inc. and through in-kind contributions made by Pistoia Alliance, the University of Michigan and Recombinant Data Corporation.

Potential long-term sources of funding to support the open source tranSMART community include industry, government and philanthropy that require sister non-profit 501(c)(6) and 501(c)(3) organizations. The U-M and Pistoia are actively working with legal counsel to determine optimal organizational and governance structures that leverage the existing 501(c)(6) Pistoia Alliance and creation of a new 501(c)(3) foundation. A Board of Directors with Executive Officers is being formed. An operations team and working groups that are representative of the consortium will also be established. A rational member-based organizational fee structure has been developed and will be implemented. Several companies have indicated willingness to participate. Grants and contracts for focused code development for government and industry sponsors is anticipated to offset the cost of the core developer and dissemination teams. Training workshops will also be offered to increase funding cash flow.

501(c)(6) Non-Profit Organization

The Pistoia Alliance will serve as the 501(c)(6) organization that will represent the private component of the proposed public private partnership. It will accept monies (membership dues, contributions) from industry to support the tranSMART open source community. It also will represent the needs of life science companies, vendors and publishers in the development and support of tranSMART as a data sharing and analytical platform for clinical and translational research.

501(c)(3) Non-Profit Organization

The 501(c)(3) organization will represent the public component of the proposed public private partnership. It will accept philanthropic donations from private foundations and individuals. It also will provide the legal structure for accepting government grants and contracts (NIH, FDA, NSF, EU) to support the development of the tranSMART open source platform. The 501(c)(3) organization will have a board of directors, executive officers, operational team and working groups that will guide the development of tranSMART and provide community support to the open source community representing all stakeholders. It will oversee planned sponsored R&D for several targeted government sponsors (NIH, FDA, VA).

Challenges and Opportunities

- *Defining and prioritizing driving biological problems across stakeholders* -- to guide platform development and analytical capabilities with corresponding funding investment.
- *What data?* -- FDA, NIH, not-for-profits, pharmaceutical and other companies and European organizations have data that can be or can potentially be placed into the public domain.
- *Coordination* -- of EU, US and other efforts where the whole is greater than the sum of the parts; practically this means addressing complementary requirements, achieved by tight coordination of US and EU efforts.

Brief Description of Each Panelist's Presentation

Michael Braxenthaler will provide an update on activities to establish a public private partnership, create leadership and core teams as well as activities to plan, fund, execute and coordinate global tranSMART efforts.

Magali Haas will discuss scientific imperatives for positioning the tranSMART community to be successful including driving biological problems, data sharing and interoperability, and data liquidity.

Yike Guo will provide an update on the European eTRIKS initiative including coordination of platform development activities with complementary US-based initiatives.

Brian Athey will moderate the panel. He will summarize progress towards achieving the tranSMART vision and outline the challenges and opportunities yet to be realized.

Participation Statement

I, Brian Athey (panel organizer), attest that Michael Braxenthaler, Yike Guo and Magali Haas have agreed to participate in this proposed panel.