



CONSIDERATIONS & PRACTICAL CHALLENGES IN HANDLING INCREASINGLY DIVERSE TYPES OF DATA

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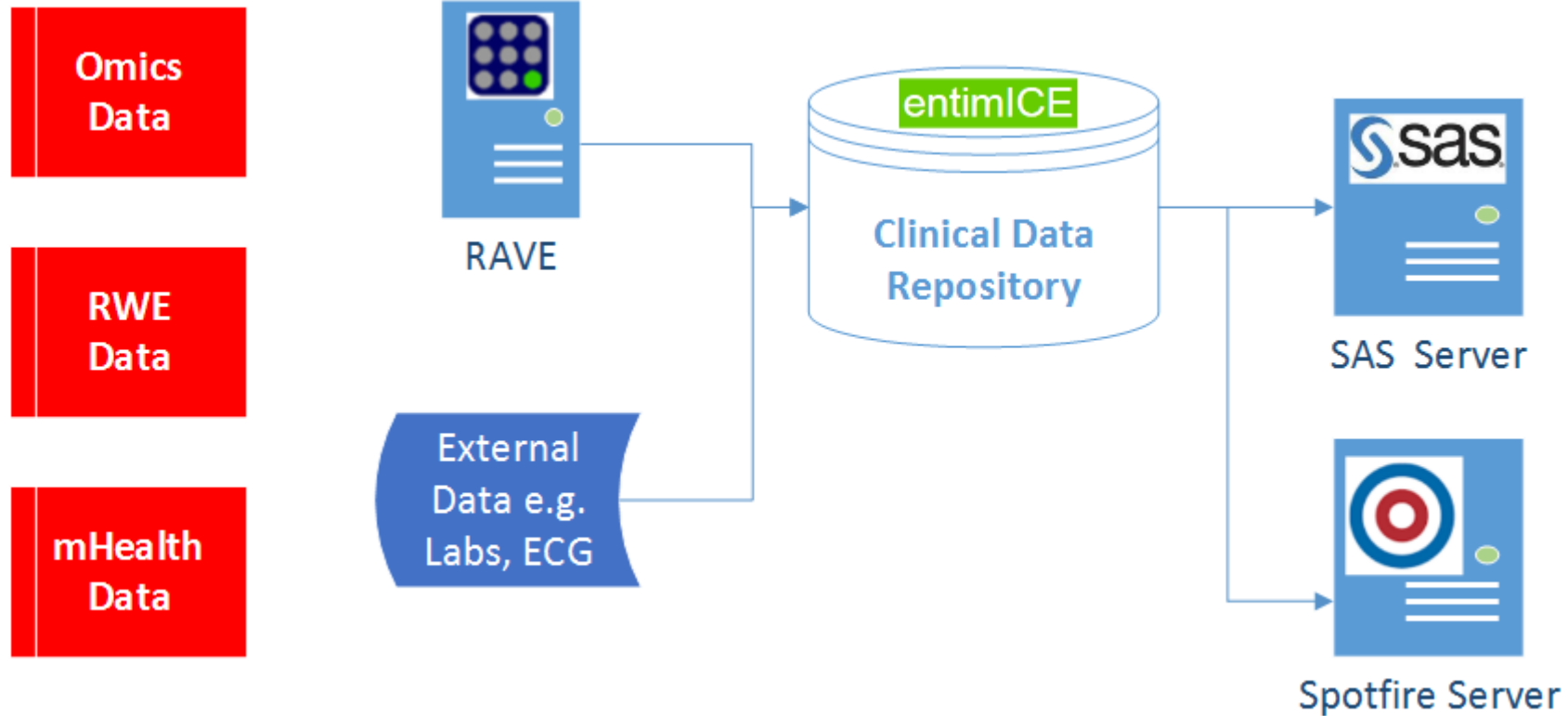
Abstract:

- ★ The platforms and approaches to handling traditional clinical trial data, supported by mature data standards are well established. However with increasing demand to collect and analyze more diverse data types within a clinical trial setting, for example mHealth and omics data or Real World Evidence data, then our current platforms and approach are not always appropriate.
- ★ We will discuss our challenges and current approach to handling these new data types at Lundbeck, including where we see the need for acquiring new skills for working with new technologies and data types and how we've adapted our organization to support this.

Overview

- ★ Introduction
- ★ New challenges in collecting and analyzing more diverse data types
- ★ High Level Architecture
 - ★ mHealth
 - ★ Omics data
 - ★ RWE data
- ★ Current Approach
 - ★ mHealth initiatives
 - ★ Handling Omics data
- ★ Organization and skills
- ★ Vision for solving these challenges at Lundbeck

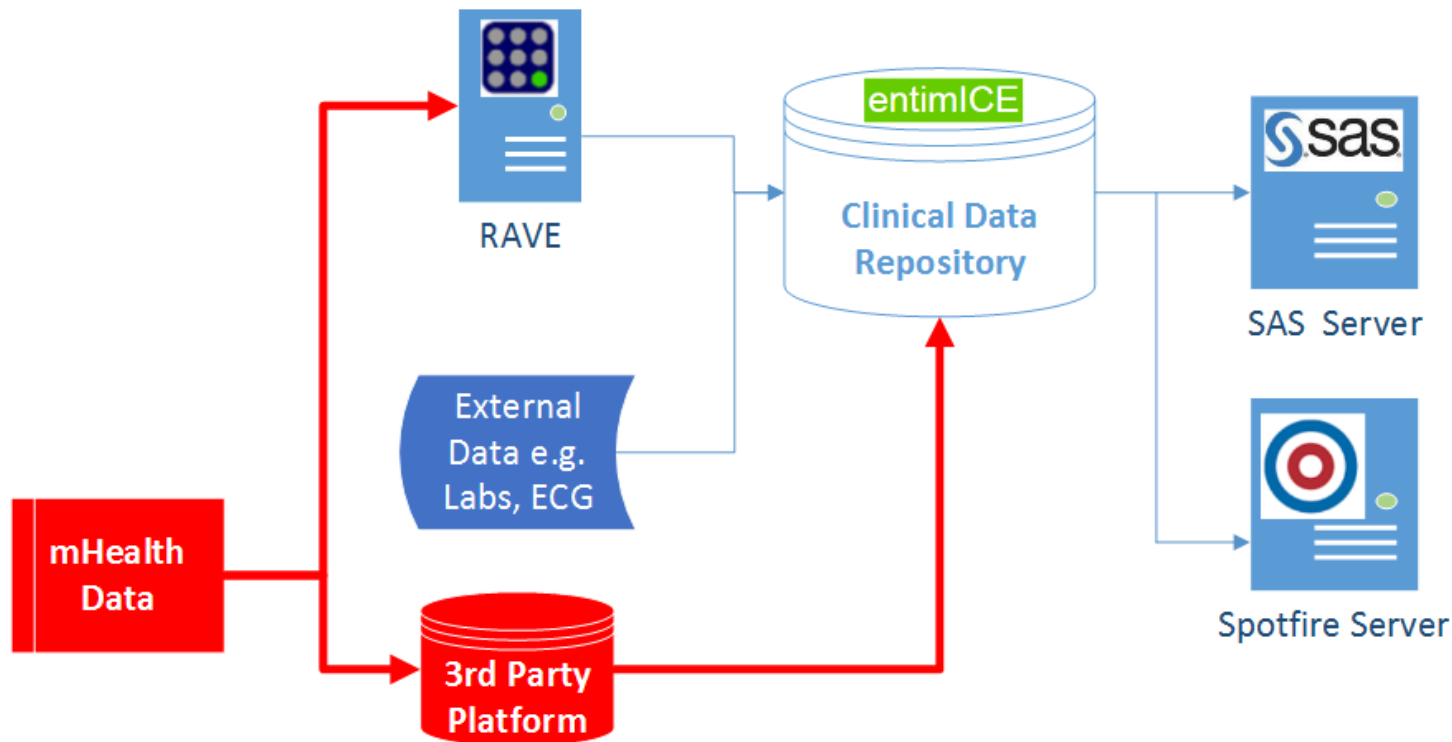
“Traditional Platform”



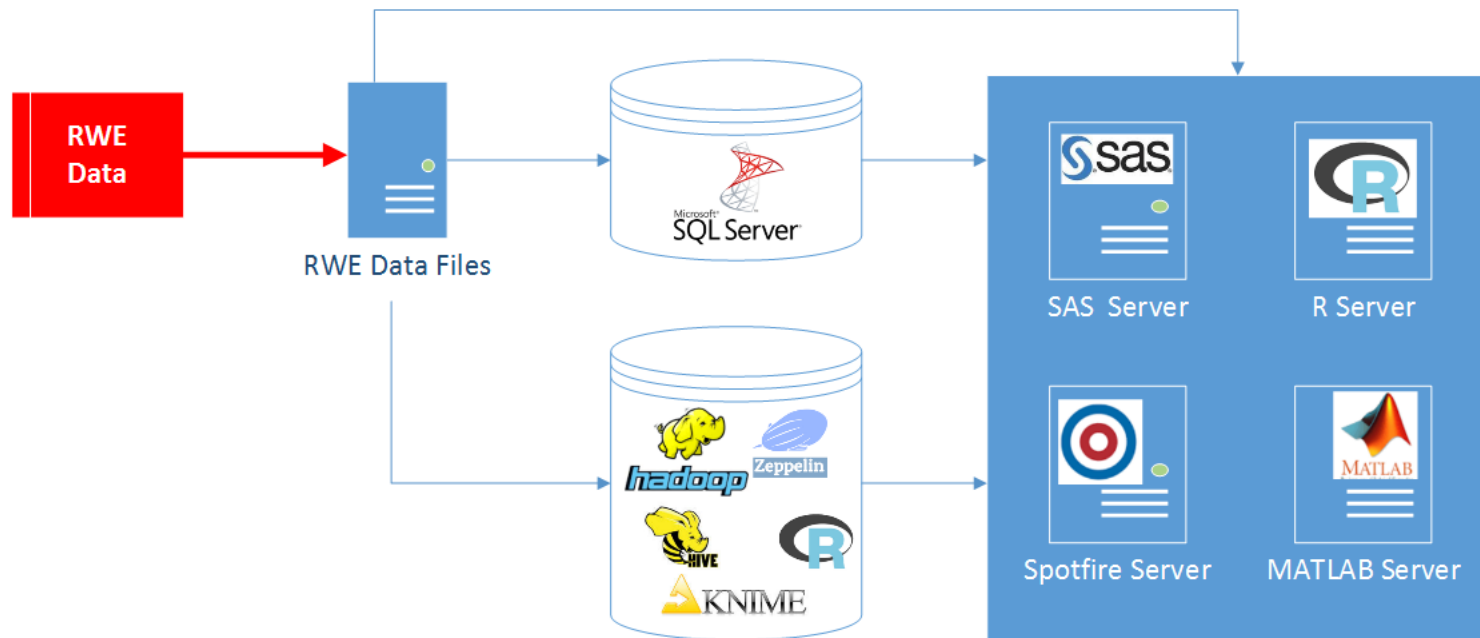
New Challenges

- ★ Data
 - ★ Large datasets
 - ★ Non-standardized
 - ★ Increased Velocity
- ★ Do we have the right Platform?
- ★ Do we have the right Skills?
- ★ Do we have the right organizational setup?

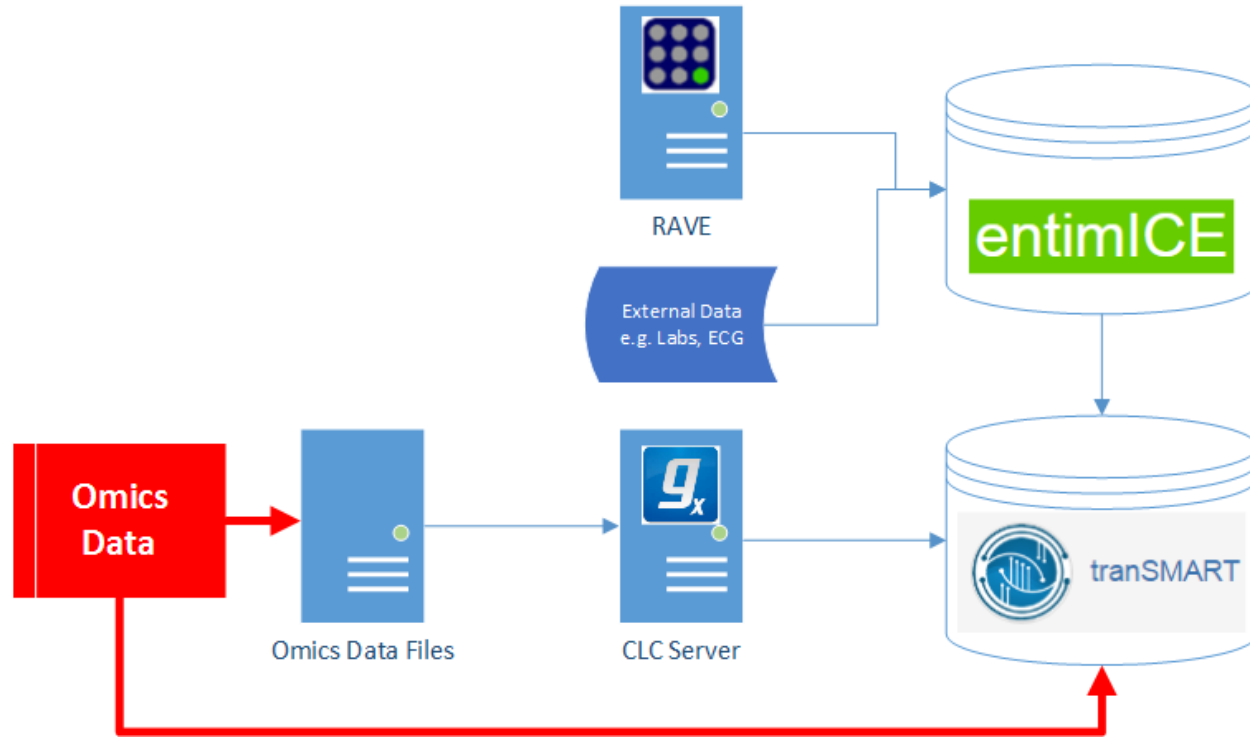
Handling of mHealth Data



Handling of RWE Data



Handling of Omics Data



THINC-it[®]

ψ PsyMate

 RADAR-CNS

Remote Assessment of Disease and Relapse - Central Nervous System

RADAR-CNS: Remote Assessment of Disease and Relapse – Central Nervous System

A collaborative research programme exploring the potential of wearable devices to help prevent and treat depression, multiple sclerosis and epilepsy

[Read more about us](#)

<http://www.radar-cns.org>

 @RADARCNS



Remote Assessment of Disease and Relapse - Central Nervous System

AIM

- Transform patient care through **remote assessment** using **wearable technologies**
- Identify **biosignatures** that can be measured remotely to **predict relapse or deterioration**

DISEASE CONDITIONS

- Major depressive disorder
- Multiple sclerosis (MS)
- Epilepsy

STRATEGY

- Create a **pipeline** for developing, testing and implementing remote measurement technologies
- Include generic data management and modelling **infrastructure** applicable to other mental and physical disorders
- **International consortium** – academic and EFPIA members
- **Patient advisory board** – feedback and expert opinion

Experience Sampling Method

- ★ Validated, structured diary technique to assess participants in relation to their environment and activity
- ★ Momentary assessment method providing repeated in-the-moment micro-measurements of affect and context in a prospective and ecologically valid manner
- ★ Multiple platform smartphone application and data platform available

The image displays three sequential screenshots of the iPsyMate application interface on a smartphone. Each screen features the 'iPsyMate' logo at the top left and a progress indicator at the top right.

- Screen 1 (1/32):** The prompt is 'I feel **cheerful**'. Below the text is a horizontal scale with seven green boxes numbered 1 to 7. Under box 1 is the text 'Not at all', under box 4 is 'Moderate', and under box 7 is 'Very'.
- Screen 2 (18/32):** The prompt is 'What am I doing (just before the beep)?'. It lists several activities with checkboxes: 'resting', 'work, school' (checked), 'housekeeping, shopping', 'hygiene', 'eating, drinking', 'active relaxation', 'passive relaxation', 'something else', and 'nothing'.
- Screen 3 (30/32):** The prompt is 'Since the last beep I have used'. It lists substances with checkboxes: 'Caffeine', 'Nicotine', 'Alcohol', 'Medication', 'Other substance', and 'Nothing of these' (checked).

Each screen has a green 'OK' button at the bottom and a green arrow labeled 'Previous' at the bottom left.



The application emits a signal ('beep') at a random moment in each of ten time blocks between 07:30 am and 10:30 pm. The signal prompts participants to fill in self-assessments automatically shown on the device display

THINC-it

THINC-it: A simple “gamified” tool to assess cognitive dysfunction in MDD that can be used in General clinical practice by non experts in cognitive dysfunction or MDD

★ Four brief, reliable tests of:



Episodic memory



Working memory



Attention

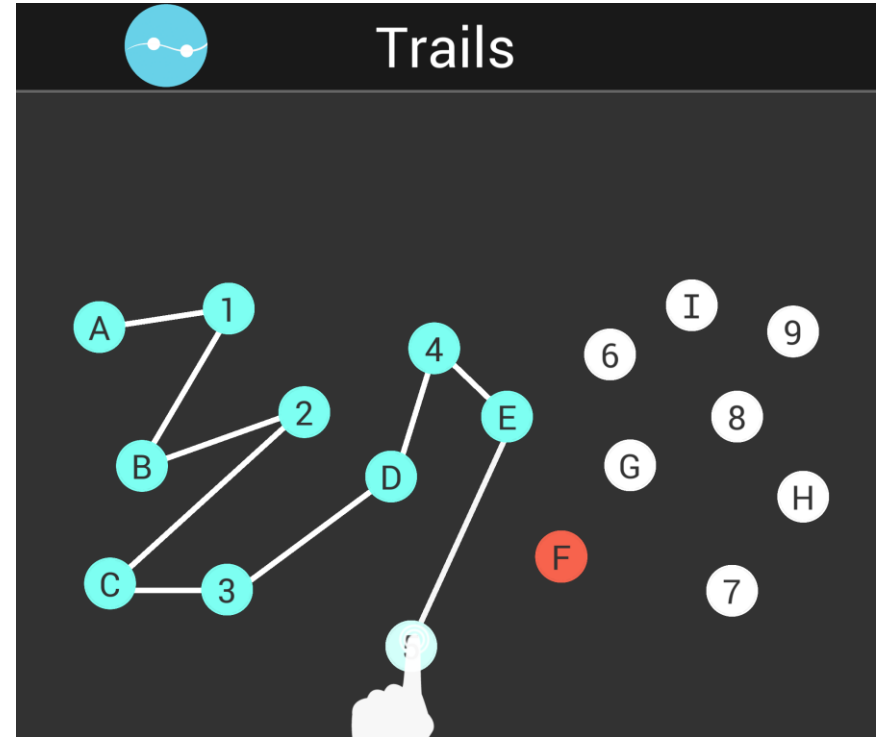
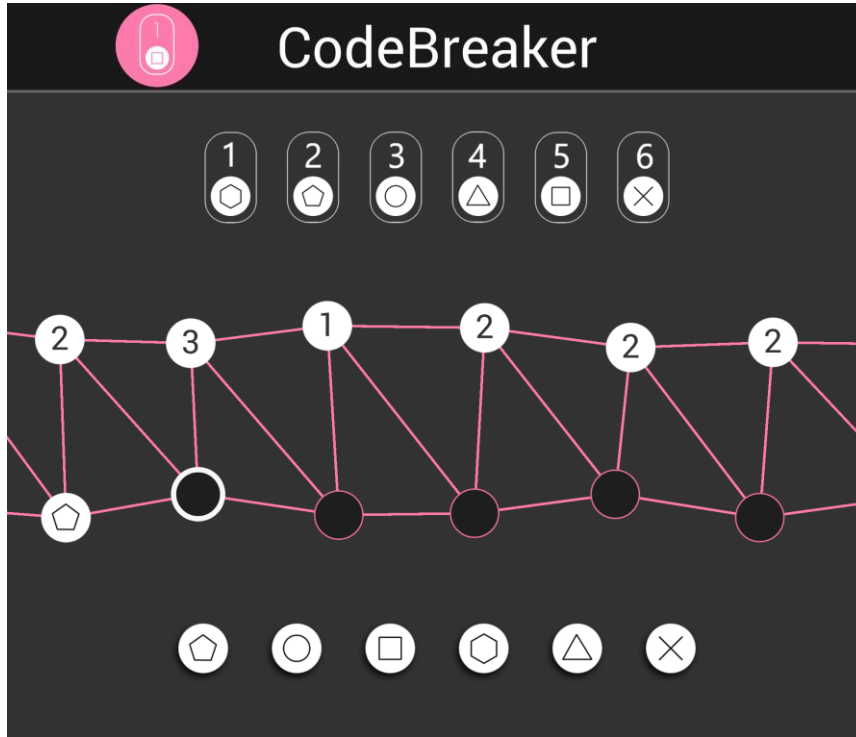


Executive functions



More information and download tool at: <http://thinc.progress.im>





Medidata Hackathon 2016

- ★ Medidata organized a hackathon in April 2016, in parallel with the Medidata European Symposium, allowing attendees to develop a functioning mobile app that makes use of Medidata's AppConnect SDK
- ★ The AppConnect SDK allows integration of custom mobile health apps (iOS and Android) with Medidata's backend
- ★ Intro to the hackathon was on the afternoon of first day of conference, and presentation was on the third day around lunch time
- ★ The Lundbeck team (team "Viking") was one of the three teams that "hacked" an app during the hackathon.





Our Ide

★ Mobile A

★ Symptom

★ Patient

★ Clinic

★ Behavior

★ Cour

meas

★ Compliance

★ Patient

presc

★ Patient I

★ Remi

Home > And The First Medidata Symposium Hackathon Winner Is...

And The First Medidata Symposium Hackathon Winner Is...

May 23, 2016

[Ross Rothmeier](#)

Comments

Share:



This year at [European Symposium](#) marked the very first Medidata Symposium Hackathon.

Symposium attendees were asked to create a mobile app to support clinical research using the recently released [Medidata AppConnect software development kit](#).

Ross Rothmeier, Medidata's vice president of technology solutions, served as chair for the technology track and the master of ceremonies of the Hackathon. Here's his recap of the event.

By all accounts, the hackathon went very, very well. At the outset, we had well over 40 attendees in the orientation session. Some were curious, others were ready to dive in and hack. Ultimately, participants developed two applications with four teams participating. All of them had fantastic ideas!

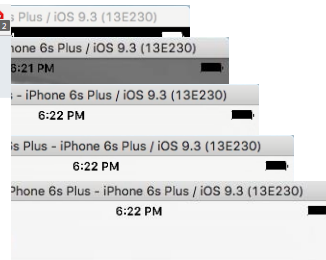
The teams met and collaborated over the course of two days. We held scrum sessions with Medidata experts to help them work through ideas and technical questions, and enjoyed a midnight hacker snack on the first day of the Symposium.

The atmosphere was electric on the day of the reveal as everyone was curious to see what the hackers had made, and I dare say they were not disappointed!

The grand prize was awarded to team Viking (aka Lundbeck) who developed a fully functioning IOS app that helped assess depression patients' responsiveness to reminders. By cleverly using the unlock feature of the iPhone, they could gauge how responsive patients were to reminders, and they sent the data directly to Rave. The UI was polished, and the code was well developed. It was just amazing.

Runners up from [SGS Life Science Services](#) created an Android app that assessed compliance with gestures (writing a Z or a question mark on the mobile phone) to gauge coordination and compliance, which again sent data directly into a Rave form. It was both clever and innovative, and it was also the first completed app in the hackathon.

Teams from Janssen and CTS/ValueLabs had innovative ideas that highlighted patient engagement. Despite not finishing their apps in time for various reasons, they were very engaged throughout the process. The teams clearly were thinking along the lines of Bristol-Myers Squibb Global Clinical Operations VP and Symposium keynote speaker Peter Ronco's challenge to tangibly show patient centricity in their work.



Unlock

2 since 2016-04-30 18:22:01

Submit

Medidata Messages My Profile Help Home Logout
User: Paula Petcu (Power User)

Inactivate Page

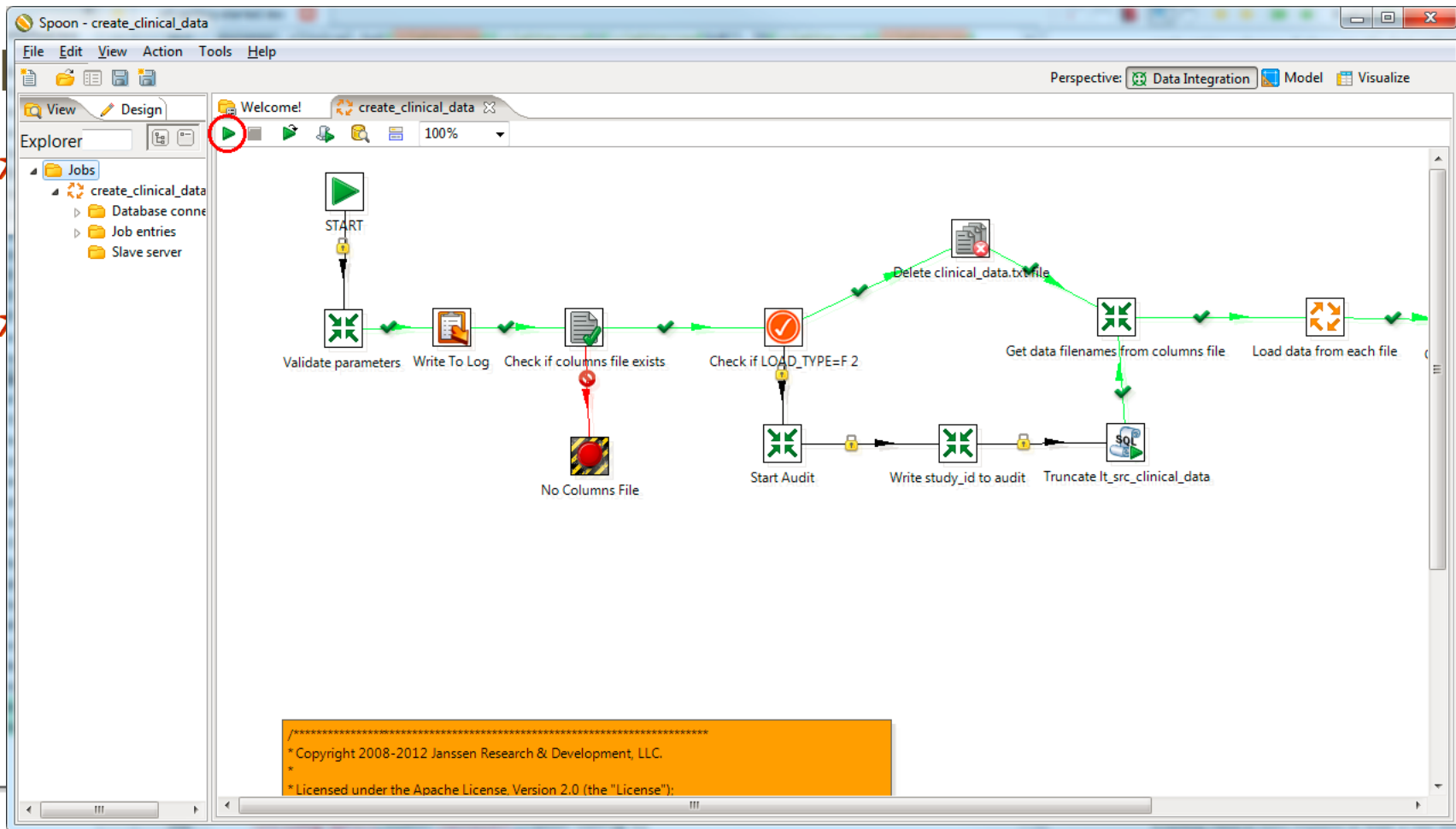
Save Cancel

tranSMART

- ★ Open source platform initially developed by Johnson&Johnson to integrate omics data with clinical data
- ★ Continuously developed by the tranSMART Foundation and user community (incl. Sanofi, Pfizer, Takeda, Roche)

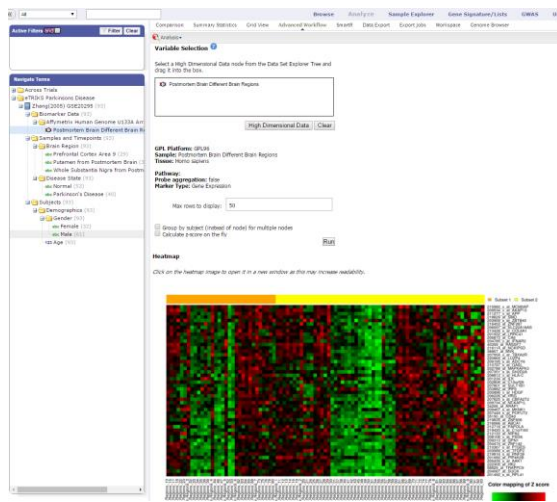
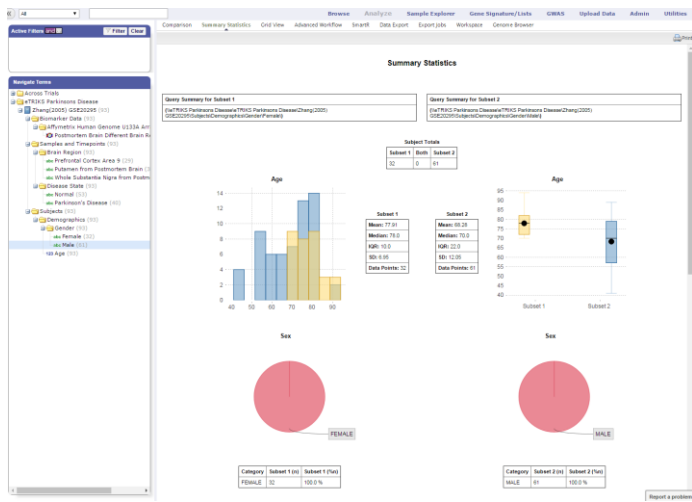


- ★ We envision that tranSMART will be used for data storage, data exploration and data sharing, as well as simple hypothesis testing and cohort selection.
- ★ Advanced analytics on the data can be done in R/Matlab/SAS/Spotfire/other by connecting to tranSMART's API



Exploring Data in tranSMART

★ tranSMART includes a **web interface** to explore and share the data and do some simple analytics (for example for subset selection), as well as a **programming interface** (REST API) that allows the data to be further analyzed in other tools



<https://github.com/tranSMART/tranSMART-rest-api/>

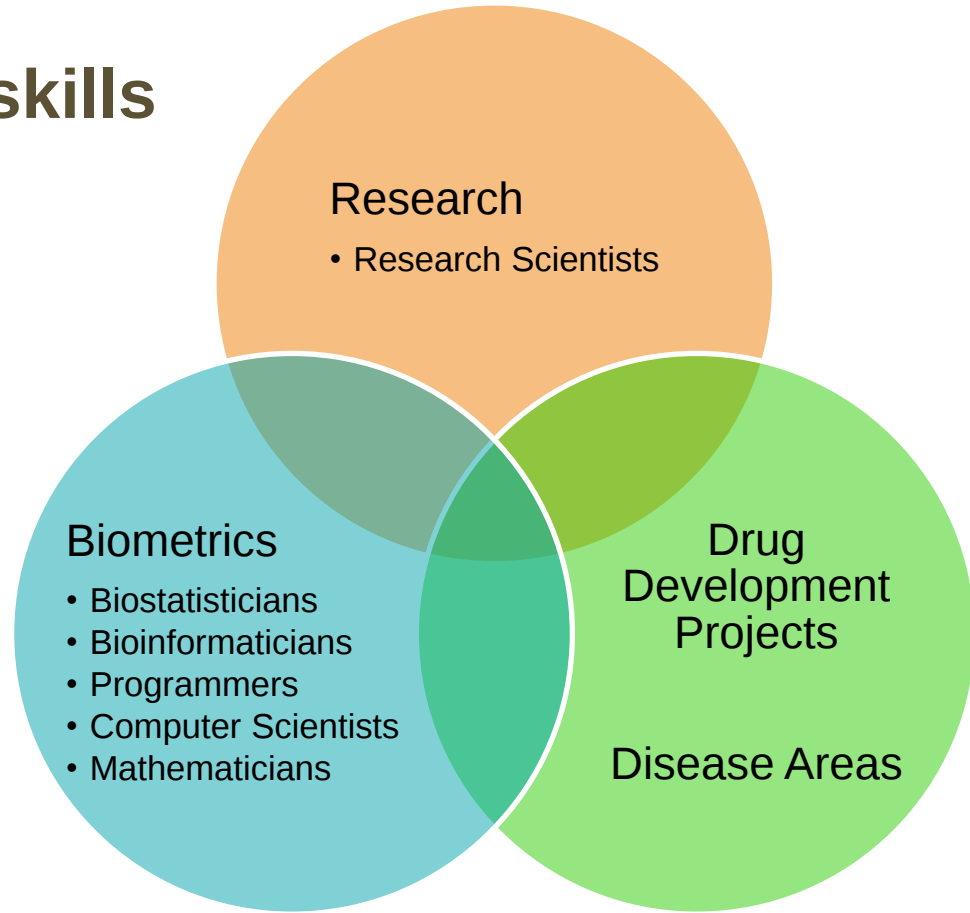
Available calls for the tranSMART RESTful API

The following is a list of all HTTP requests that can be made to a tranSMART RESTful API. All URI's are relative to your tranSMART server's URI (eg. <http://some.tranSMART.server/tranSMART>).

The return message's body will contain JSON with additional HAL format, with the exception of the request for high dimensional data (see section below).

Call	HTTP request	Description
get all studies	GET /studies	returns information on all available studies
get single study	GET /studies/{studyId}	returns information on a single study
get all concepts	GET /studies/{studyId}/concepts	returns information on all concepts for a study
get single concept	GET /studies/{studyId}/concepts/{conceptPath}	returns information on one concept for a study
get all subjects	GET /studies/{studyId}/subjects	returns information on all subjects for a study
get single subject	GET /studies/{studyId}/subjects/{subjectId}	returns information on one subject for a study
get subjects with concept	GET /studies/{studyId}/concepts/{conceptPath}/subjects	returns the subjects which have data for this concept
get all observations	GET /studies/{studyId}/observations	returns all clinical observation values for a study

Organization and skills



Vision

