Overview of Computational Sciences
The Working Groups

- Learn about each of the PhUSE CS Working Groups
  - http://www.phusewiki.org/wiki/index.php?title=CSS_Working_Groups
- SCE is one project within the **Emerging Trends & Technologies Working Group**
  - ET&T WG: http://www.phusewiki.org/wiki/index.php?title=Emerging_Technologies
  - Statistical Computing Environments http://www.phusewiki.org/wiki/index.php?title=Statistical_Computing_Environments

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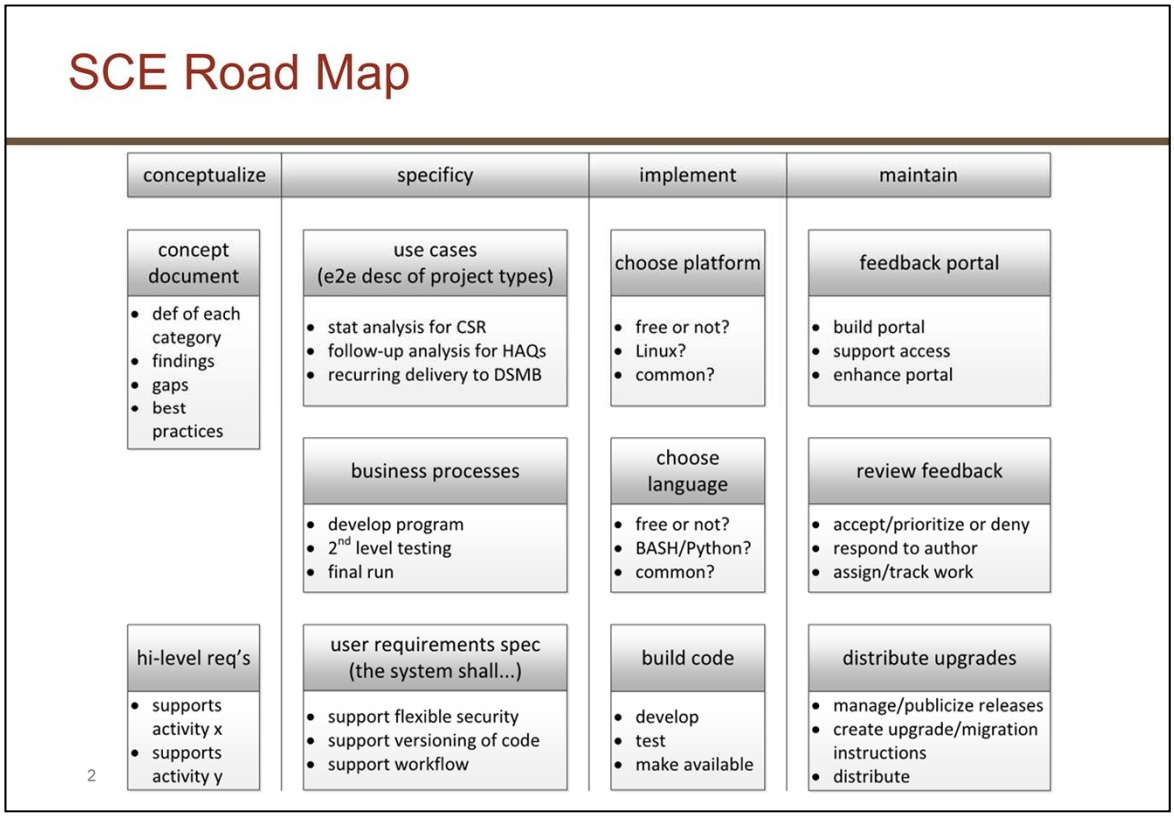
In addition to the PhUSE.eu website, you can learn more about the Computation Sciences Working Groups from the PhUSEwiki.org site.

http://www.phuse.eu/cs-working-groups.aspx

http://www.phusewiki.org/wiki/index.php?title=CSS_Working_Groups



The SCE Road Map comprises four main phases

1. Conceptualization, including the SCE Whitepaper "State of the SCE"
2. Specification, the focus of the EU CSS 2016 in the form of drafting use cases
3. Implementation
4. Maintenance

The objective of phases 1 & 2 is to describe an ideal SCE using use cases and requirements, which could be used to direct the development of an open source solution or be used by vendors to develop a solution (variations on phase 3). Maintenance, of course, follows either variant.

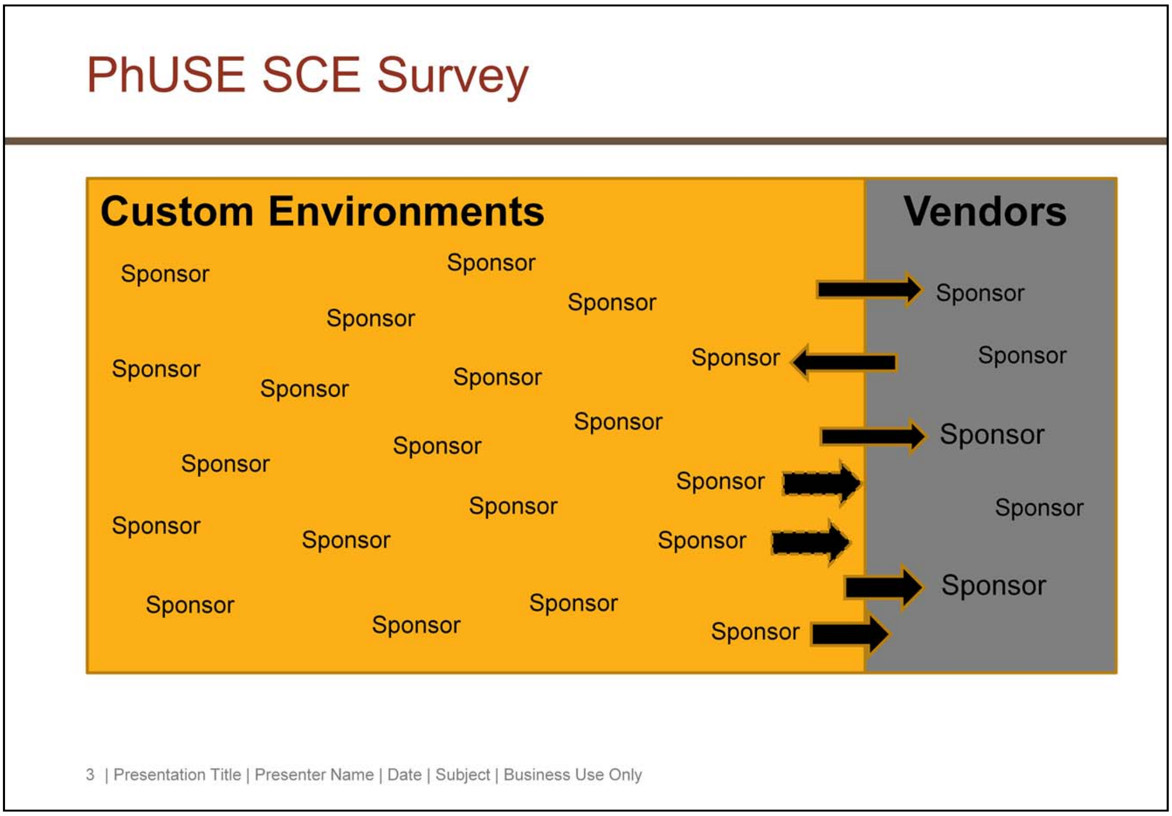
See also the PhUSE SCE Whitepaper "State of the SCE"

Published on the PhUSE Wiki project site:

http://www.phusewiki.org/wiki/index.php?title=Statistical_Computing_Environments

Direct link to docx:

http://www.phusewiki.org/wiki/images/0/00/State_of_the_SCE_-_Final.docx



<u>Software - system or interface</u>

Use of a system or interface was mixed with:

19% - Commercially available software (3x SAS Drug Development, 2x Oracle Life Sciences Hub)

41% - Custom software

41% - No software

People were generally satisfied with the ease of use (93% somewhat or very user friendly/easy to use) and performance (100% acceptable or excellent).

Number of users ranged from 20 to 1,500 and concurrent users ranged from 5 to 1,000.

Details from the PhUSE SCE Whitepaper "State of the SCE"

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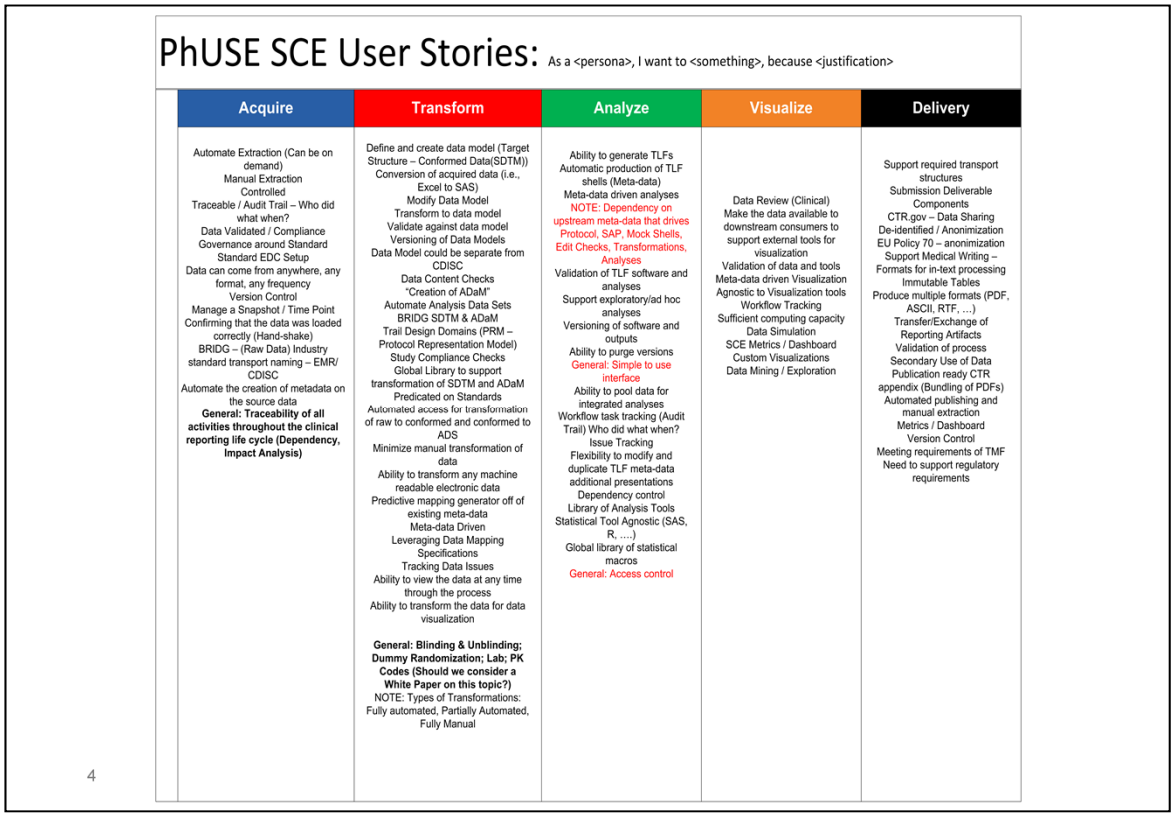

PhUSE SCE User Stories: As a <persona>, I want to <something>, because <justification>

Acquire	Transform	Analyze	Visualize	Delivery
Automate Extraction (Can be on demand) Manual Extraction Controlled Traceable / Audit Trail – Who did what when? Data Validated / Compliance Governance around Standard Standard EDC Setup Data can come from anywhere, any format, any frequency Version Control Manage a Snapshot / Time Point Confirming that the data was loaded correctly (Hand-shake) BRIDG – (Raw Data) Industry standard transport naming – EMR/ CDISC Automate the creation of metadata on the source data **General: Traceability of all activities throughout the clinical reporting life cycle (Dependency, Impact Analysis)**	Define and create data model (Target Structure – Conformed Data(SDTM)) Conversion of acquired data (i.e., Excel to SAS) Modify Data Model Transform to data model Validate against data model Versioning of Data Models Data Model could be separate from CDISC Data Content Checks "Creation of ADaM" Automate Analysis Data Sets BRIDG SDTM & ADaM Trail Design Domains (PRM – Protocol Representation Model) Study Compliance Checks Global Library to support transformation of SDTM and ADaM Predicated on Standards Automated access for transformation of raw to conformed and conformed to ADS Minimize manual transformation of data Ability to transform any machine readable electronic data Predictive mapping generator off of existing meta-data Meta-data Driven Leveraging Data Mapping Specifications Tracking Data Issues Ability to view the data at any time through the process Ability to transform the data for data visualization **General: Blinding & Unblinding; Dummy Randomization; Lab; PK Codes (Should we consider a White Paper on this topic?)** NOTE: Types of Transformations: Fully automated, Partially Automated, Fully Manual	Ability to generate TLFs Automatic production of TLF shells (Meta-data) Meta-data driven analyses NOTE: Dependency on upstream meta-data that drives Protocol, SAP, Mock Shells, Edit Checks, Transformations, Analyses Validation of TLF software and analyses Support exploratory/ad hoc analyses Versioning of software and outputs Ability to purge versions General: Simple to use interface Ability to pool data for integrated analyses Workflow task tracking (Audit Trail) Who did what when? Issue Tracking Flexibility to modify and duplicate TLF meta-data additional presentations Dependency control Library of Analysis Tools Statistical Tool Agnostic (SAS, R, ….) Global library of statistical macros General: Access control	Data Review (Clinical) Make the data available to downstream consumers to support external tools for visualization Validation of data and tools Meta-data driven Visualization Agnostic to Visualization tools Workflow Tracking Sufficient computing capacity Data Simulation SCE Metrics / Dashboard Custom Visualizations Data Mining / Exploration	Support required transport structures Submission Deliverable Components CTR.gov – Data Sharing De-identified / Anonimization EU Policy 70 – anonimization Support Medical Writing – Formats for in-text processing Immutable Tables Produce multiple formats (PDF, ASCII, RTF, …) Transfer/Exchange of Reporting Artifacts Validation of process Secondary Use of Data Publication ready CTR appendix (Bundling of PDFs) Automated publishing and manual extraction Metrics / Dashboard Version Control Meeting requirements of TMF Need to support regulatory requirements

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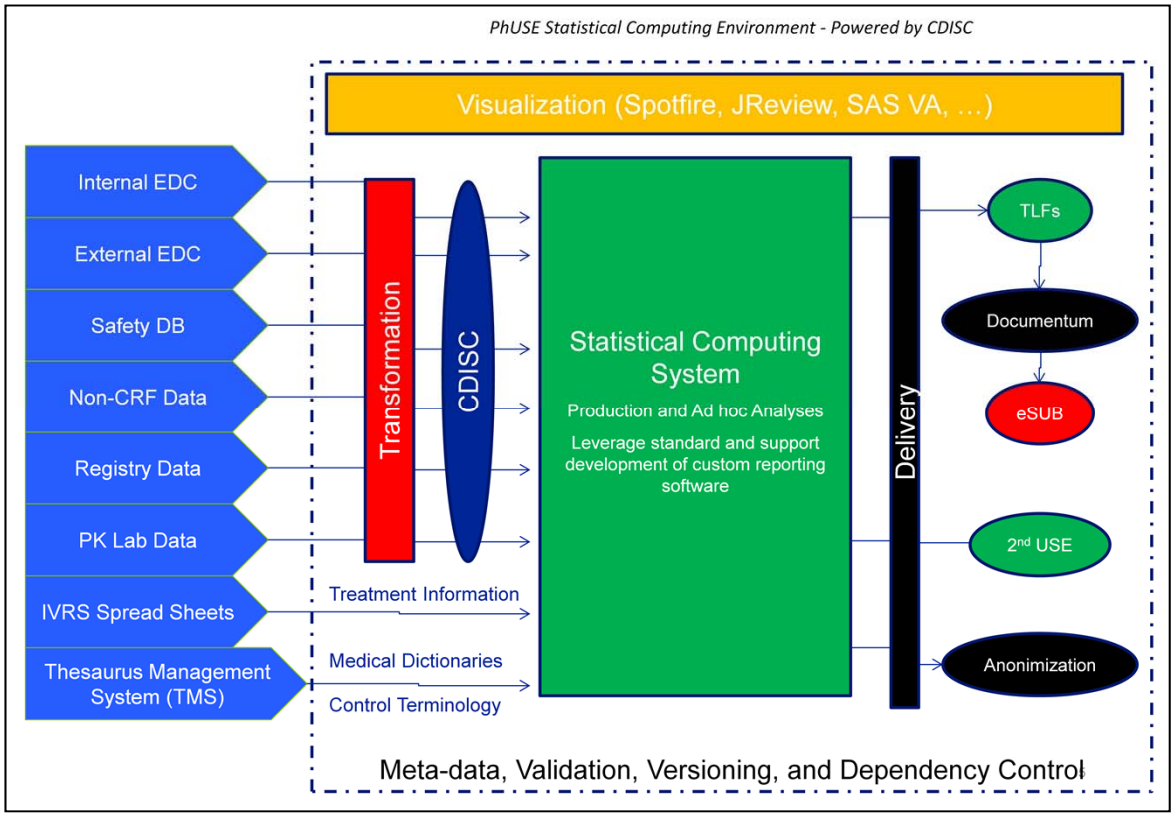
Outcome of USA CSS 2016, March

Step 1: Initial brainstorming around primary categories of stories for users of statistical computing environments.

In advance of EU CSS 2016, June, we propose 2 additional categories

- **System / Non-functional**, such as controlling access, verifying training requirements satisfied to gain access, etc.
- **Planning**, such as registering planned outputs to estimate effort, track progress, etc.

The June, 2016, EU CSS will focus on developing these 2 new categories, in addition to detailing use cases for the Acquire and Transform categories.



Visual summary of the SCE components discussed during the March 2016 CSS.