

Review and Highlights of the 2016 Survey of the Top 20 Biopharmaceutical Companies' Statistical Computing Environments (SCEs)

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Acknowledgement

Thanks to Novartis for the support in conducting this survey.



Agenda

- Background (15 min)
 - Survey Methodology
 - Demographics of Participants
 - Composite vs. Single-vendor Concept
- Interactive Anonymized Industry Survey Summary (30 min)
 - Composite vs. Single-vendor Analysis (15 min)
 - Business Requirements Fitness Analysis (15 min)

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Participants Demography

- **Which type of organization do you belong to?**

- 1) Biopharmaceutical with >200 SCE users
- 2) Biopharmaceutical with <200 SCE users
- 3) CRO or Consultancy
- 4) Software
- 5) Other or Independent

Project Plan

Class of Users

Class of Users	Region	Region
1 Admin - S		
2 Light Use		
3 Business		
4 Power Us		
5 Other		

Generic Requirements

Phase	Actual	Internal	External	Total	Grand Total
Design & Scoping	Business	IT	Business	IT	
Select	-	-	-	-	-
Implement					
Maintain					

Costs (USD '000s)

Phase	Software	Hardware	Hosting	Internal FTE	External FTE	Other fees
Design						
Select						
Implement						
Maintain						

Support FTEs

Generic Requirements	SCE	% Achieve
0.Ability to control user access to system	SCE	100%
1.Ability to control user access to content	SCE	75%
2.Ability to control version control and dependency tracking of submission related artefacts	SCE (and extra tools)	5%
3.Ability to integrate with other data sources	SCE	100%
4.Ability to centrally store and manage metadata and data transformation functions	Excel	0%
5.Ability to configure a business process	Process & WI documents	25%
6.High performance execution	R, Matlab, Nonmem, Ansys, Stan	0%
7.Tracking and metrics portal to allow the planning, creation and execution of a	Excel & Access and PC SAS	0%

Stats Reporting Requirements

Generic Requirements	SCE	% Achieve
1.Perform robust and accurate statistical analysis	SCE	100%
2.Produce outputs of that analysis and to design the look and style	SCE	100%
3.Facility to automate these capabilities (1. & 2.)	SCE	40%

Data Transformation

Generic Requirements	SCE	% Achieve
1.Perform simple transformations	SCE	100%
2.Perform complex transformations	SCE	100%
3.Facility to automate these capabilities (1. & 2.)	SCE	40%

Data Storage

Generic Requirements	SCE	% Achieve
1.Storage for Clinical data	SCE	100%
2.Storage of downstream artefacts required for regulatory compliance	SCE	100%

Data Visualization

Generic Requirements	SCE	% Achieve
1.Perform simple static review of data	SCE +JMP +PC	100%
2.Perform complex dynamic review of data	SCE +JMP +PC	80%

Grand Total

Category	Value
1.466	1.466
1.135	1.135
2.601	2.601

Notes:

Either core in top tab

Survey Participants

Many thanks to all of them!



What We're Thinking.....

But no survey can capture

SCE is pre-competitive and cannot be an industry advantage

CSR is only 40% of our work

We're not a software company

We want to remain agile and integrate changes quickly

Whilst important, Advanced Data Visualization is not a priority

We want to be first-in-class in study design and efficiency, not in audit readiness

Our partnership with one vendor simplifies licensing and support management

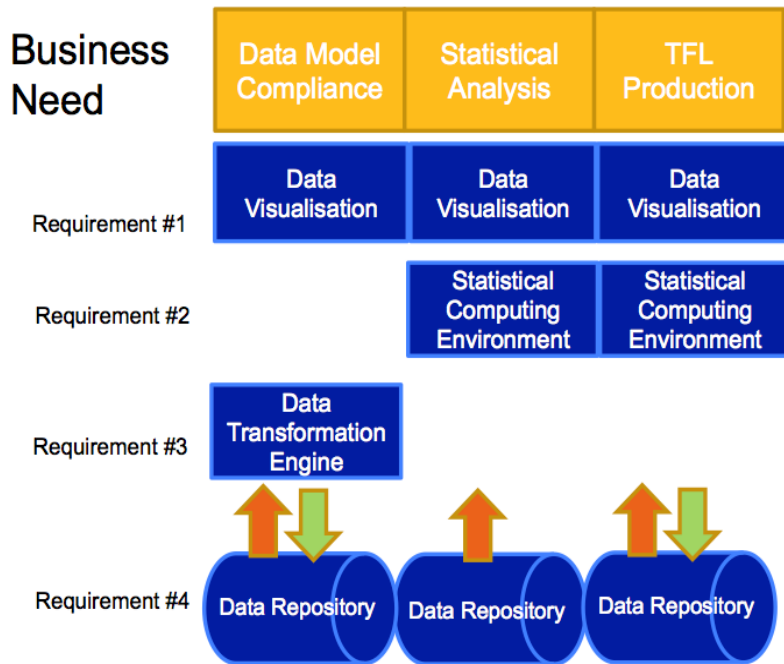
SCEs can be over-complex and have performance issues

We trust people more than workflow and technology

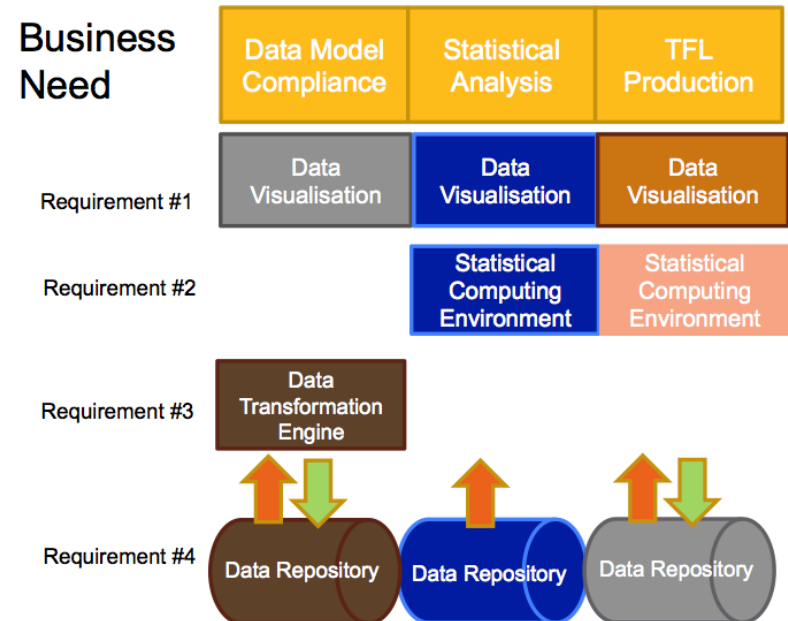
Single-vendor and Composite Solutions



Single-Vendor Solution



Composite Solution



"Building Blocks" of Composite Solutions

Tracking & Metrics	Workflow
Statistical Packages	Data Visualization
High Performance	
Data Extraction & Transfer	Data Transformation
Access Control	
Version Control	
Audit Trail	
Storage of Clinical Data & Programs	Metadata

Industry Survey – of SCE System Owners

Statistical Computing Environment (SCE) detailed analysis

Identified*¹

20 Published list of
Top 20 Pharma by
Sales 2014

Responded*²

15 Companies
engaged with
the Survey

5 No
Contact

73% (11)

Composite Solutions*³

27% (4)

Single-Vendor Solutions*⁴

*¹ Aim to survey our peer group

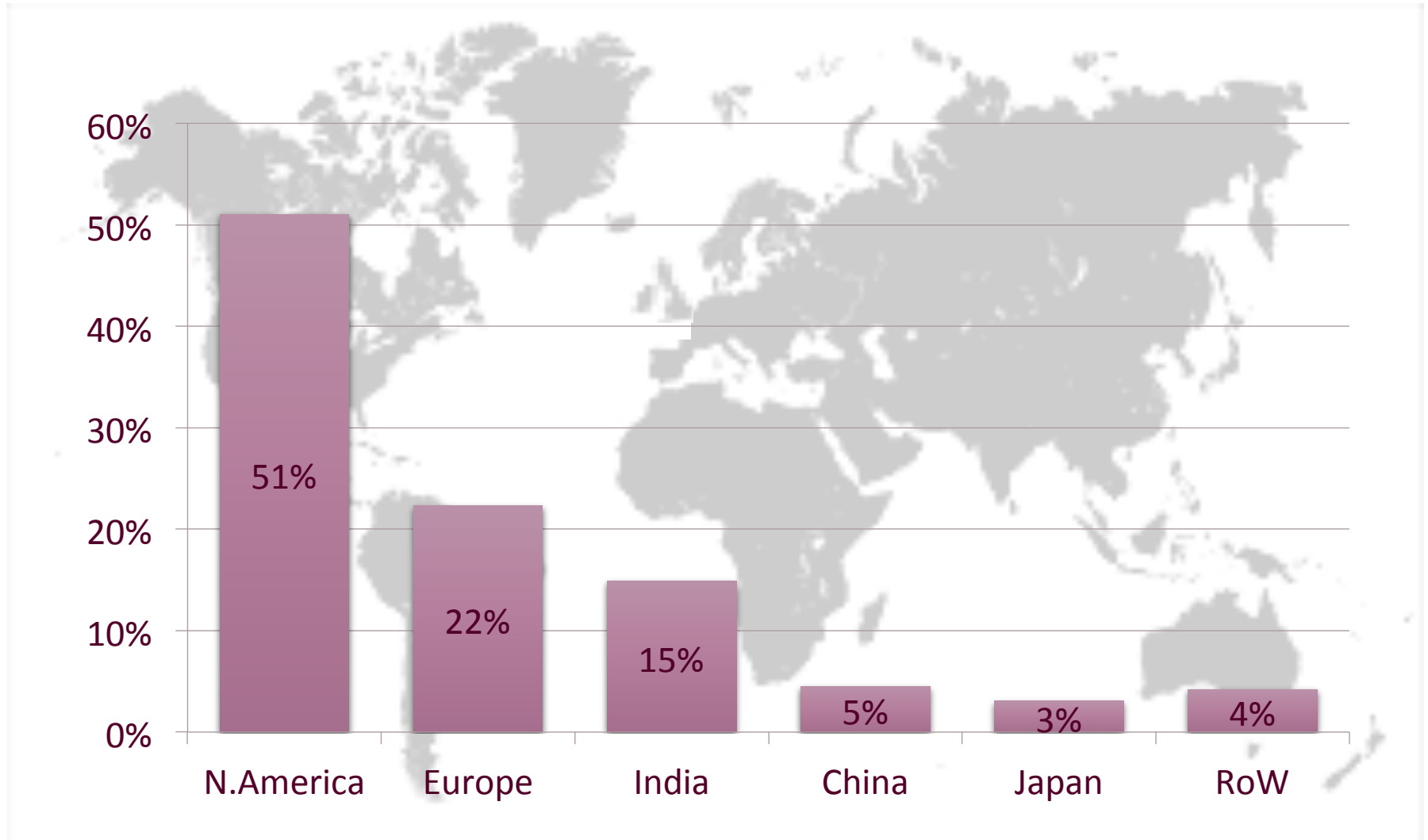
*² Excel Survey tool & 1hr interview

*³ 3/11 companies use a single-vendor solution for a given region or therapeutic area

*⁴ 3/4 companies were about to go into Production at the time of the survey

Number of Users per Region

Survey +11,000 / Estimated 20,000



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Single Vendor vs. Composite Solutions?



Single-Vendor Solution



Composite Solution

Why Single-Vendor?

4 companies / 15 interviewed

Single-Vendor Solutions Benefits

- Software upgrade, maintenance & support handled by vendor
- Access management simplified to CRO and externals
- Single source of data
- Simplified licensing management

Why Composite?

11 Companies / 15 interviewed

For Strategic Reasons (??/11)

- Remain independent and agile

Lack of Requirements Fit (??/11)

- None of the solutions available at the time met the requirements during evaluation

Why Composite?

11 Companies / 15 interviewed

For Strategic Reasons (4/11)

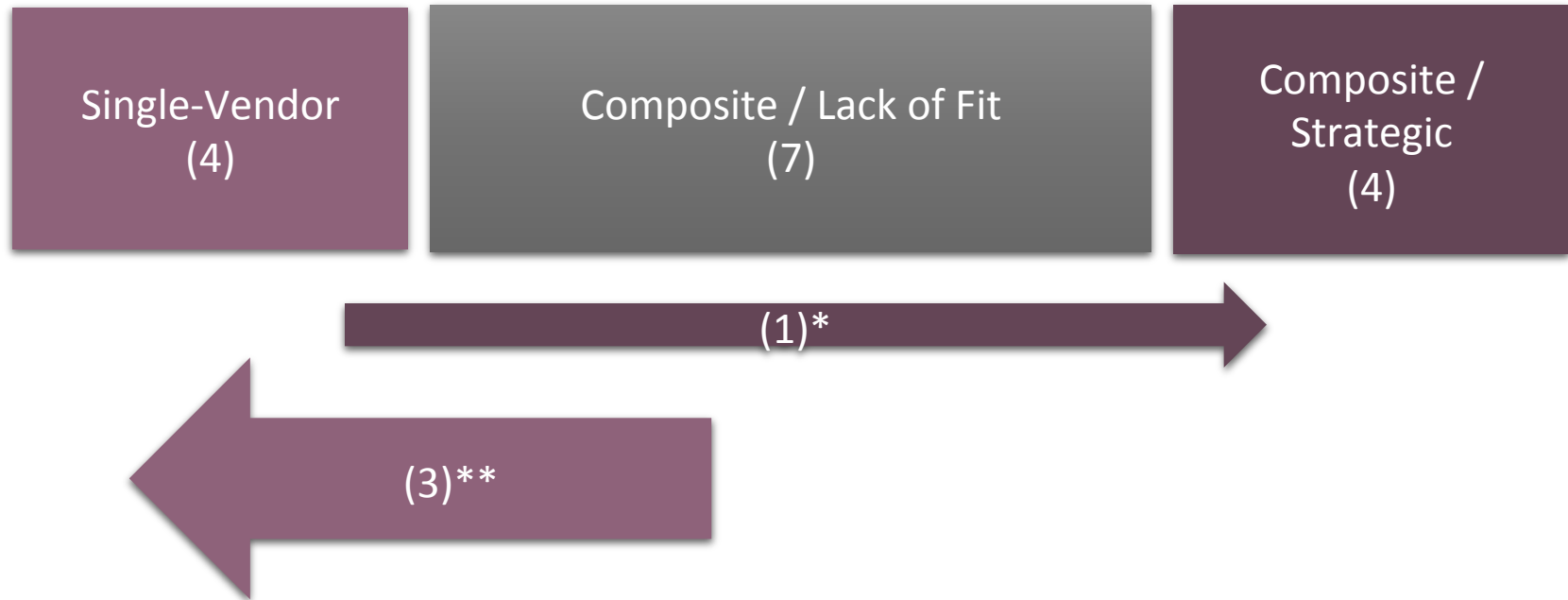
- Remain independent and agile

Lack of Requirements Fit (7/11)

- None of the solutions available at the time met the requirements during evaluation

Single Vendor vs. Composite Solutions?

Summary



* Number of Companies that have recently moved from Single-Vendor to Composite / Strategic

** Number of Companies that have recently moved from Composite / Lack of Fit to Single-Vendor

Perceived Fit to Business Requirements – 1 of 4

Based on tab "12 – Req (%)" in Industry Survey

High Fit	Median = 100%
Medium Fit	50% < Median < 100%
Low Fit	Median = 50%

Generic Requirements

0. Ability to control user access to system

1. Ability to control user access to content

2. Automatic version control and dependency tracking of submission related artefacts

3. Ability to integrate with other data sources

4. Ability to centrally store and manage metadata and data transformation functions

5. Ability to configure a business process

6. High performance execution

7. Tracking and metrics portal to allow the planning, creation and execution of activities

4. Ability to centrally store and manage metadata and data transformation functions

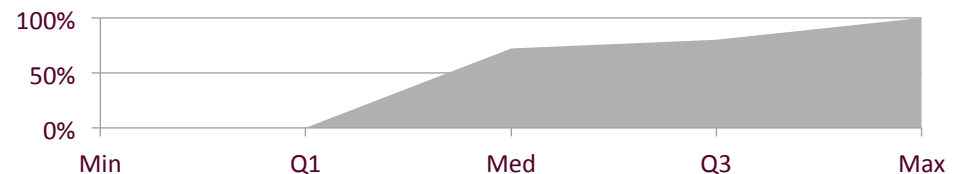


5. Ability to configure a business process



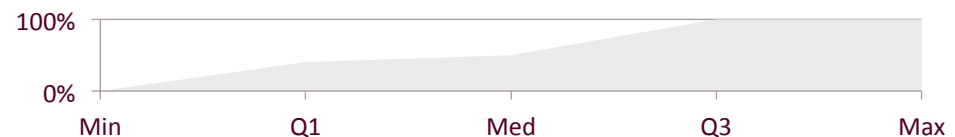
2. Automatic version control and dependency tracking of submission related artefacts

6. High performance execution



3. Ability to integrate with other data sources

7. Tracking and metrics portal to allow the planning, creation and execution of activities



Perceived Fit to Business Requirements – 2 of 4

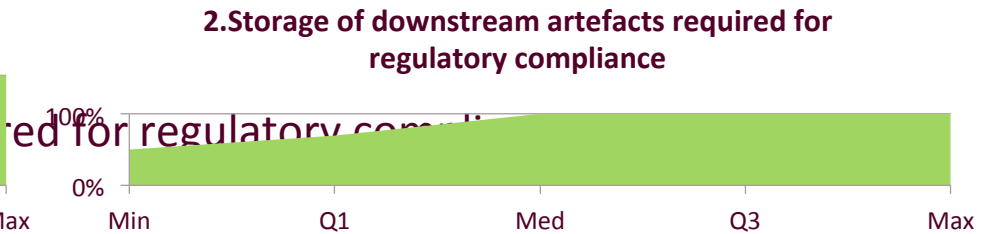
Based on tab "12 – Req (%)" in Industry Survey

High Fit	Median = 100%
Medium Fit	50% < Median < 100%
Low Fit	Median = 50%

Data Storage

1.Storage for Clinical data

2.Storage of downstream artefacts required for regulatory compliance



Data Transformation

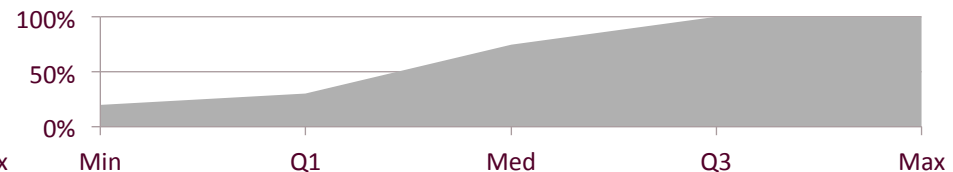
1.Perform simple transformations

2.Perform complex transformations

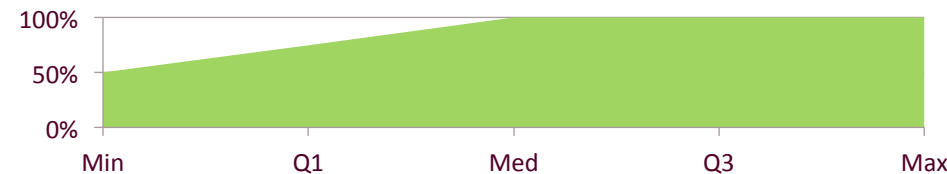
3.Facility to automate these capabilities (1. & 2.)

1.Perform simple transformations

3.Facility to automate these capabilities (1. & 2.)



2.Perform complex transformations



Perceived Fit to Business Requirements – 3 of 4

Based on tab "12 – Req (%)" in Industry Survey

High Fit	Median = 100%
Medium Fit	50% < Median < 100%
Low Fit	Median = 50%

Stats Reporting Requirements

1. Perform robust and accurate statistical analysis

2. Produce outputs of that analysis and to design the look and style

3. Facility to automate these capabilities (1. & 2.)

Min Q1 Med Q3 Max Min Q1 Med Q3 Max

3. Facility to automate these capabilities (1. & 2.)

Data Visuali

1. Perform simple static review of data

2. Perform complex dynamic review of data

1. Perform simple static review of data

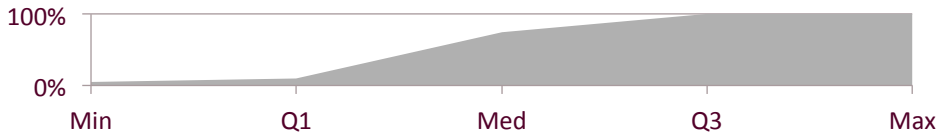
2. Perform complex dynamic review of data

Min Q1 Med Q3 Max

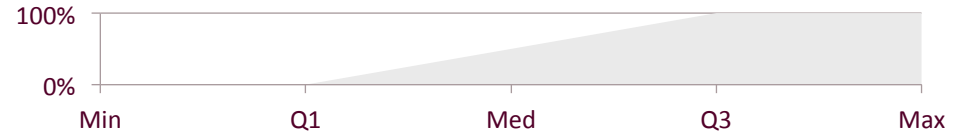
Min Q1 Med Q3 Max

Exigent Requirements

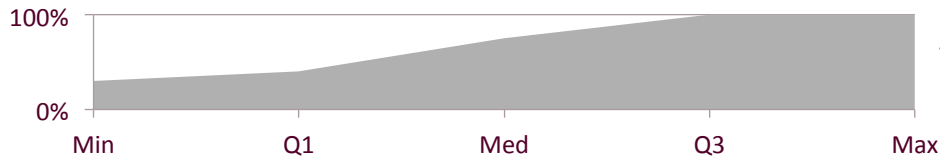
Automatic version control and dependency tracking of submission related artefacts



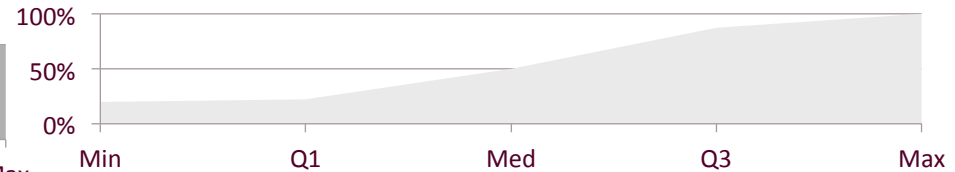
Ability to centrally store and manage metadata and data transformation functions



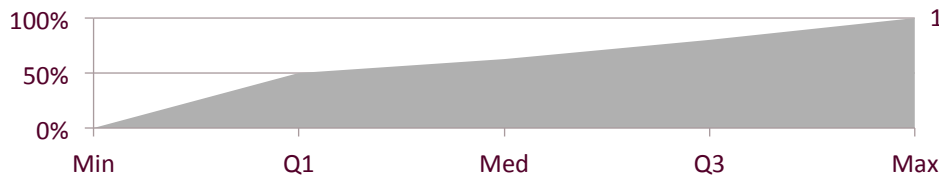
Facility to automate TFL generation



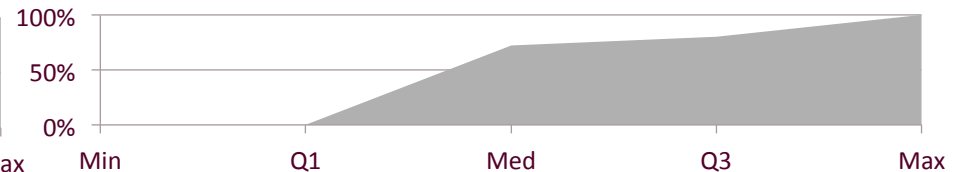
Ability to configure a business process



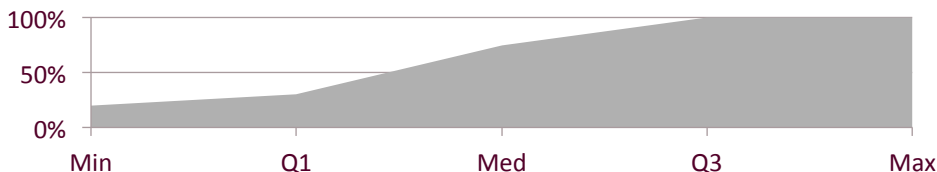
Perform complex dynamic review of data



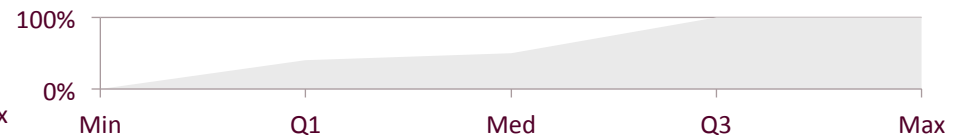
High performance execution



Facility to automate data transformation



Tracking and metrics portal to allow the planning, creation and execution of activities



Main Findings

1 of 2

- Versioning and Traceability are important requirements that are not always met at a functional level.
- Metadata management, workflow & business process management and planning/tracking/metrics are not well addressed by current solutions
 - Largely addressed by MS Excel!
- Data Visualization is often seen as not part of SCE and is managed separately. Advanced Data Visualization tools do not seem to be a priority for Biostatistics & Programming departments.

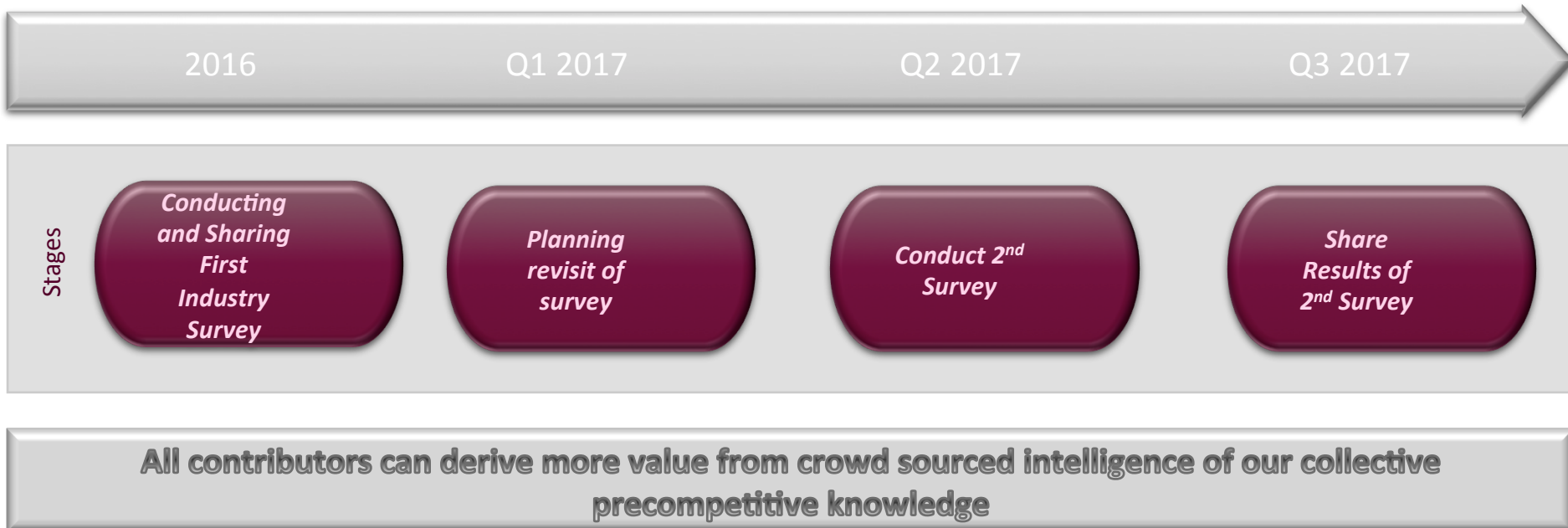
Main Findings

2 of 2

- Most top-20 companies are still developing and managing Composite systems (11/15).
- There was not a clear requirement towards moving to single-vendor solutions although this is a desire from a number of companies that screen the market on a regular basis and 3 companies were taking that path at the time the survey was conducted.
- There are notable efforts from vendors to and involve sponsors in requirements prioritization.

Survey of Large SCE Users

Overview of the process



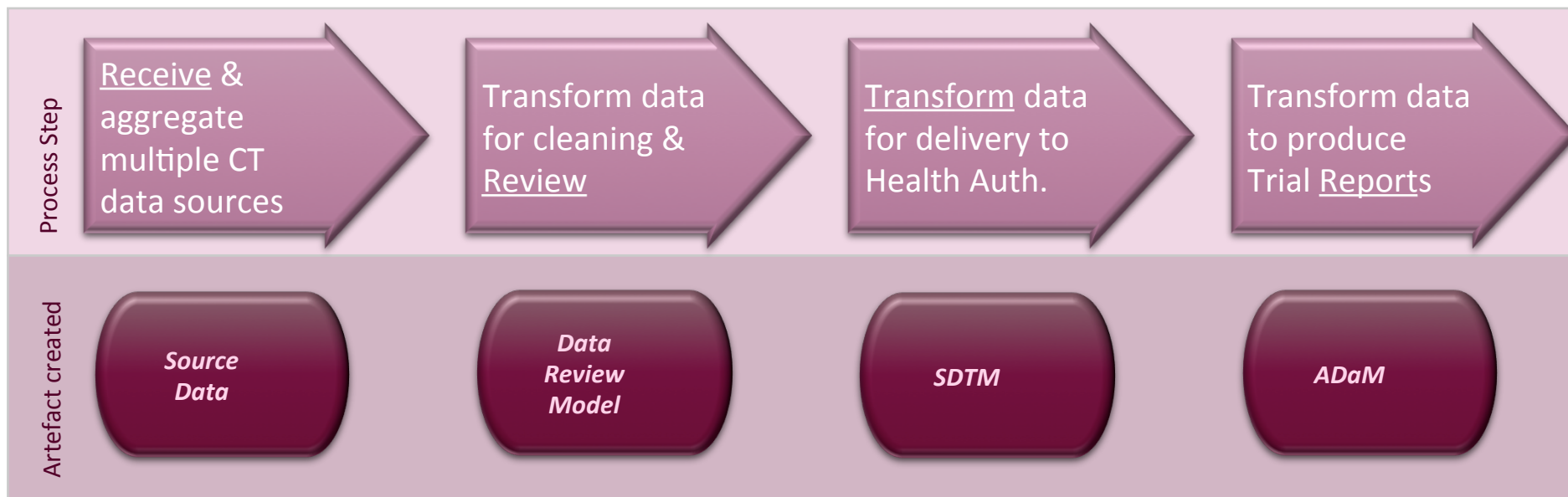
Thank You!

- **Jean-Marc Ferran**
- **James McDermott**

BACK-UP SLIDES

An Indicative End to End data flow

The value chain in clinical trials



An end to end workflow that is compliant with the Health Authority expectations and is the simplest we could present based on our collective organisational experience.

Myriad data sources

- 3rd Party Data
- ePRO,
- IRT,
- Wearables,
- EDC,
- Outsourced

Data Review Model is lean and transparent and tailored for;

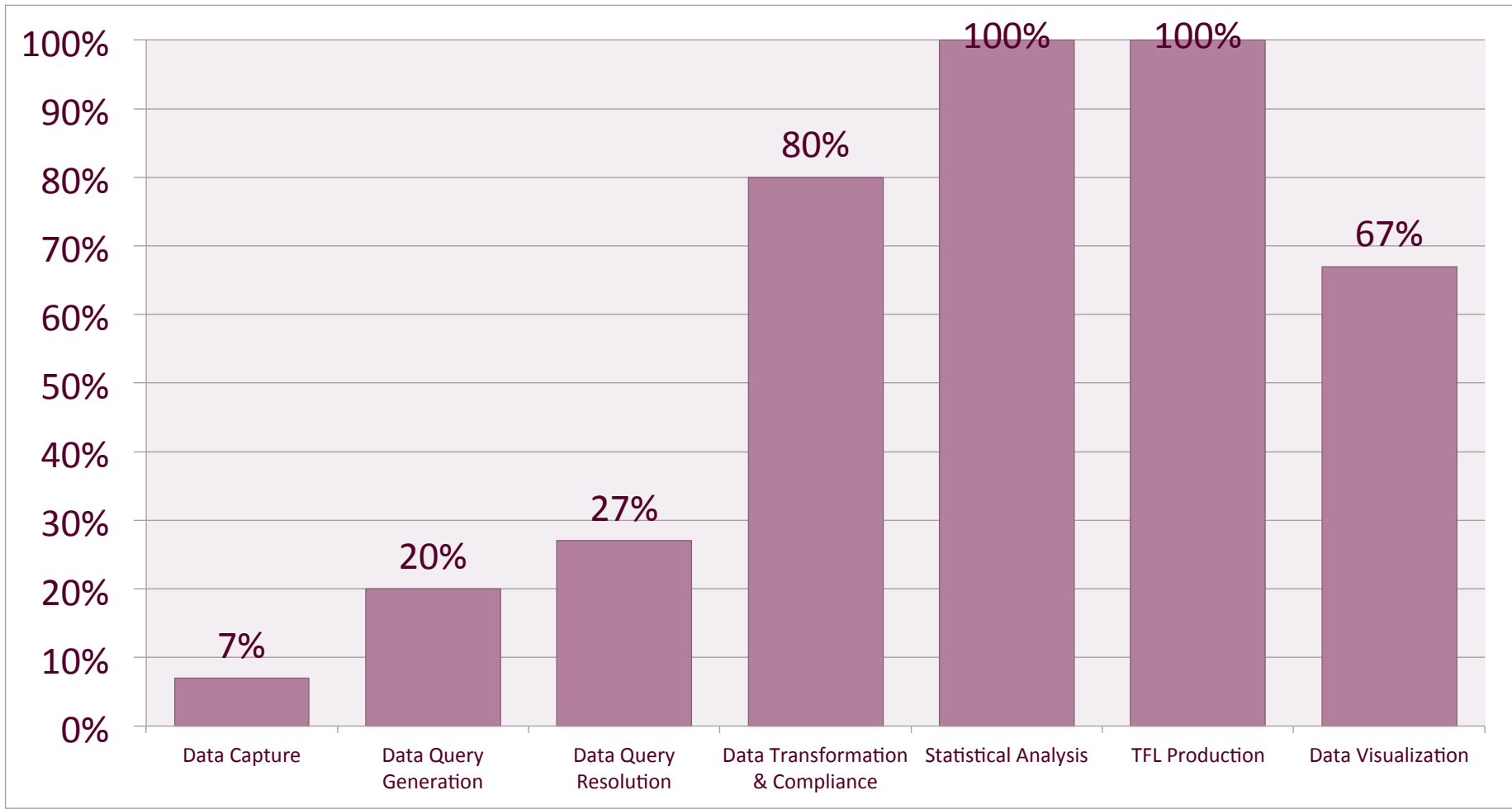
- data review,
- tracking changes,
- audit trail of data elements

CDISC model for delivery to HA.,

- Minimal required transformations and derivations must now be complete

CDISC industry Standard model for including, completed derivations & transformations for analysis and reporting

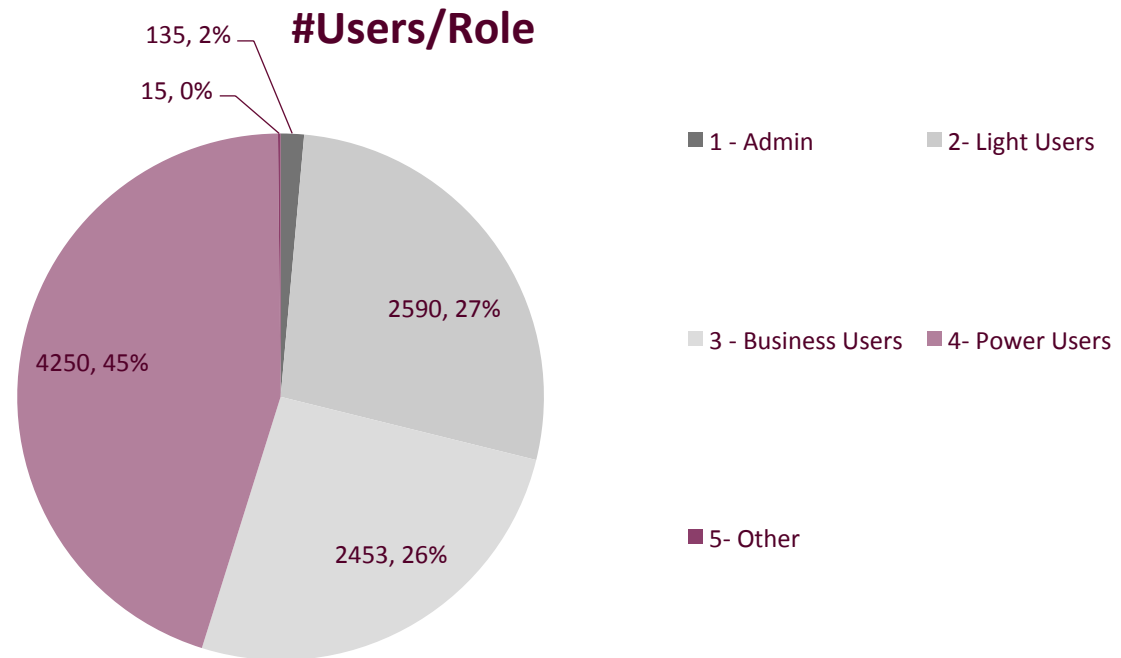
What does your SCE cover?



Number of Users by Role

Roles:

- 1 - Admin: System/user maintenance and control
- 2 - Light Users: Data Loaders and Data Reviewers
- 3 - Business Users: Statistician
- 4 - Power Users: Statistical Programmer
- 5 - Other: Any category not described in 1-4



Note: Total number will not match with previous slide as certain respondents could only provide #Users/Region

Project Timelines

Analysis & Implementation Timelines (Months)

