

The Vision of Clinical Data Science

Where will we be in 2025?

developing agile
and adaptive
process in the
modern fast-paced
data rich world

10 October 2016



A word cloud on a dark blue background featuring various terms in orange, white, and light blue. The words are arranged in a vertical, columnar fashion. The most prominent words include 'esource' (in large blue letters), 'Insourcing' (in large orange letters), and 'FOR' (in large white letters). Other visible terms include 'Sophisticated Trials', 'Conditional Approvals', 'Personalised Tx', 'Statistical Computing Environments', 'Real Life Data', 'Off-shoring', 'In-life Trials', 'Health', 'Outcomes', 'Patient Engagement', 'Life License', 'Collaborative R&D Models', 'Increased Risk Averseness', 'Open Source Tools', 'Wearable', 'Adaptive', 'Globalisation', 'Resource', and 'and Talent'.

Sophisticated Trials
Conditional Approvals
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Wearable
Adaptive
Globalisation
Resource
and Talent
FOR

workshop leaders



Chris Price



Sam Warden



Shafi Chowdhury



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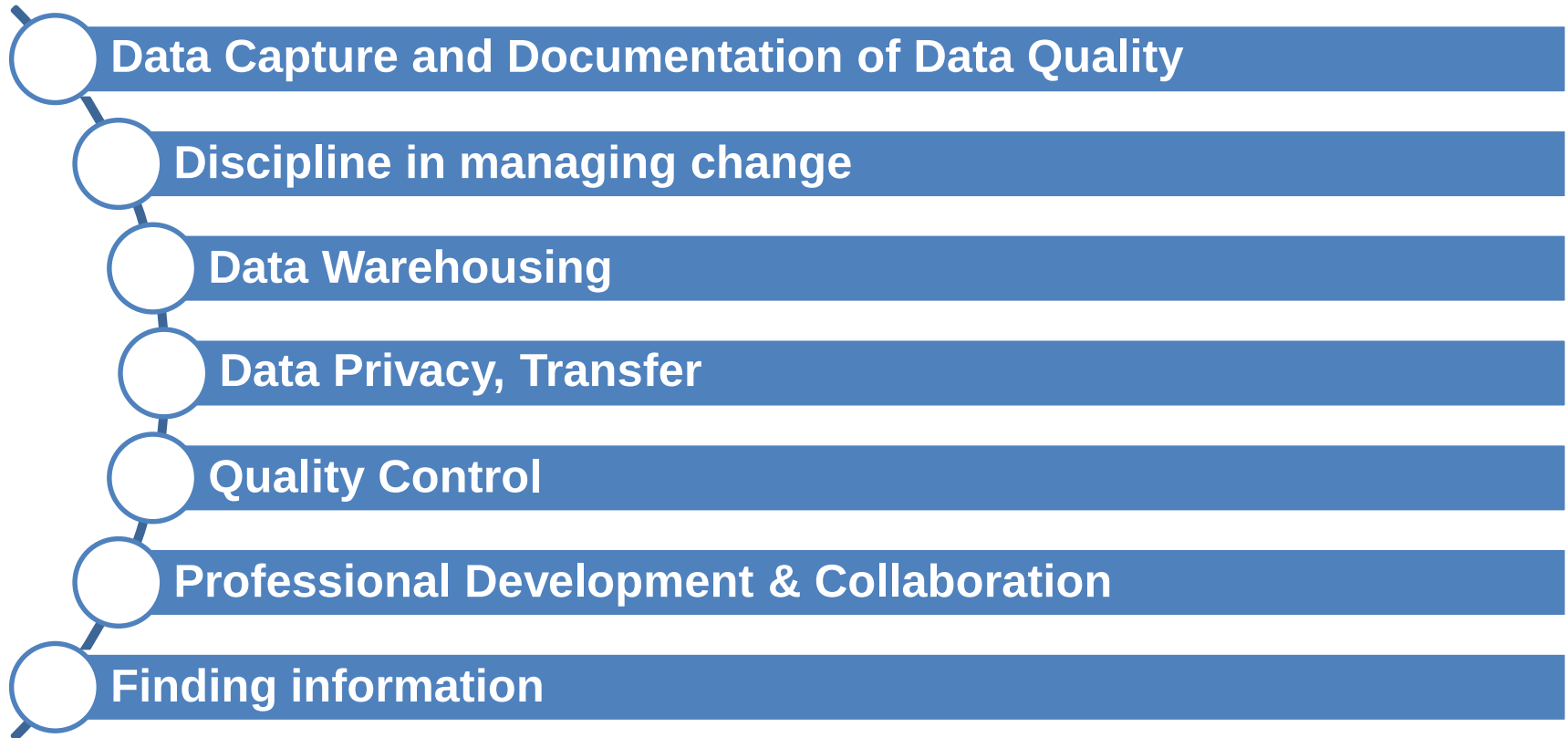


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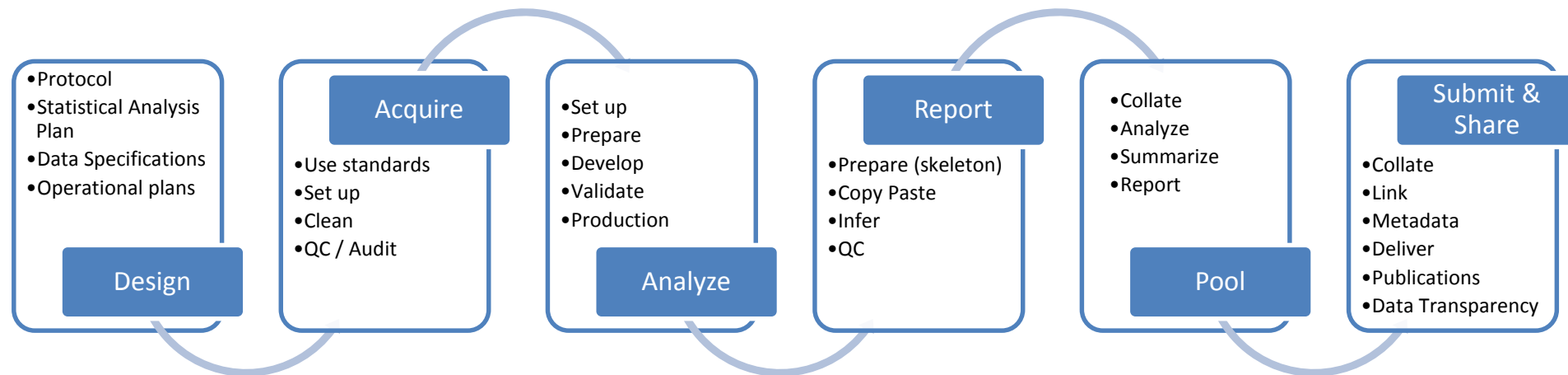
agenda

1. why do we need to change our clinical data processes?
2. theory – how do we change processes?
 - 3 quick tools you can take home
3. breakouts to challenge processes (put the theory into practice)
4. wrap up

process challenges



clinical development process



data types

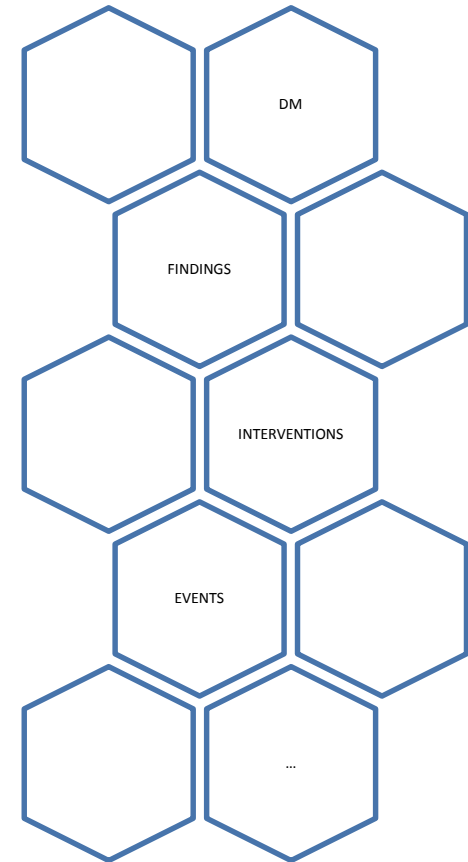
Protocol

CDASH
& LAB

SDTM

ADaM

Define.XML
Reviewers Guides



theory

1. map and challenge inputs & outputs of your process
2. examine data
3. how might we (hmw)?

'good' learning 'takes place in a climate of openness where political behaviour is minimized' (Easterby-Smith and Araujo 1999)

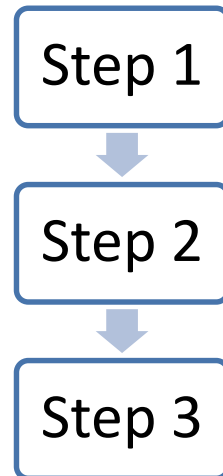


1. how do I map my process?



SIPOC*

Supplier – Input – Process – Output - Customer



*Lean Six Sigma

2. examine data



- measure outcomes
 - elapsed time
 - effort
 - defect/error rate
- look for process hotspots
 - where do issues occur?
 - rework
 - checklists and handoffs
 - long wait times
 - multiple roles involved



3. how might we (hmw) ?



- stop doing this?
 - what's the impact to : time, quality, resources / cost
- do it differently?
 - what would need to change?
 - what other impacts are there?

Step 1



Step 2



Step 3

Exercise – 1 hour

1. Split into groups and go with each facilitator (5 mins)
2. Process is prepared for you & there is a data sheet that goes with it
3. Create a SIPOC from your knowledge of the process - you can add extra steps if you need to (10 mins)
4. Examine the data and annotate your process with the information (10 mins)
5. How might we? (15 mins)
6. Report back on your ideas for steps to be removed or adjusted – 5 mins per group

What next?

- Take away these techniques
- Put them into practice within your own organizations
- Volunteer to join the Future Forum process working group

Back - up

Flipchart Notes [Basel CS Event](#)

Proposed Project 1: [Data Process in Other Industries](#)

Proposed Project 2: [Professional Dev. Roles & Collaboration](#)

Next Steps

Q&A

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Proposed Projects

Evaluation of Data Processes in Other Industries

Why? - We realize that some of the processes in the Pharma Industry are long and takes a long time to change. We want take this opportunity to see how other industries both regulated and non-regulated process their data, and update their process as data and requirements change in their industries.

Professional Development – Roles and Collaboration

Why? - This is important to ensure that the role stays relevant and continues to evolve from the past where it was primarily a programming role to the current status where we provide much more input into requirements, to the future where hopefully we will lad different tasks. Key to all this is ensuring the resource is available and has the relevant skills.

Evaluation of Data Processes in Other Industries

Project Lead = Sam Warden

Problem Statement

- Pharma is not unique in its need to collect, store and analyse data or that it has to comply with regulatory requirements. Many other industries also have a requirement to perform these activities. What could we as clinical data scientists learn from these other industries to improve our processes to make them fit for the future.

Project Description

- To develop a white paper identifying other industries that have established processes for the collection, storing and analysing data. These processes should be described and assessed for their applicability to pharma considering how they manage changes to their requirements, how data is captured, what quality control is performed, how they deal with a changing landscape and their approach to new data types plus any other areas of interest that are identified.

Professional Development – Roles and Collaboration

Project Lead = Under discussion

Problem Statement

- To allow clinical data scientists to continue to add value to the clinical development process there is a need for individuals to update their skillset to cover areas beyond the current and historic areas of competence.

Project Description

- To develop a white paper identifying processes within the clinical development lifecycle, including consideration for the future state, where statistical programmers have either not traditionally contributed to or have only participated to a limited extent where a clinical data scientist could provide valuable input. The white paper should also identify additional skills that a clinical data scientist would need to develop in order to effectively contribute to these processes.

Opportunities Identified

- Evaluation of other industries data processing
- Use & Re-use guidelines
- Defining the role of the Data Scientist
- Access to health record data
- Global single standards management as opposed to independently at each company