

Clinical Data Scientist – what it is (not)

Phuse 2015, PD04
Michaela Jahn



(Clinical) Data Scientist - Examples

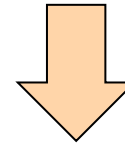
- Data Science is the extraction of knowledge from large volumes of data that are structured or unstructured, which is a continuation of the field data mining and predictive analytics, also known as knowledge discovery and data mining (KDD) – Wikipedia (search term 'Clinical Data Scientist')
- Data Science: applying the team's diverse informatics and analytical capabilities to retrieve and analyse data to support drug project decision making, drug and platform development. Data Science capabilities include Bioinformatics, Imaging Informatics, Biostatistics, Data integration and visualization, Text-mining, Information Science – Roche pre-clinical and early clinical development.
- Data Scientist: Articulate insights from HR data to help guide decision-making for the business; design HR data warehouse analytics, yield a pipeline of opportunities and people projects - People Analytics Team with Human Resource
- **Clinical data scientist has a comprehensive knowledge of all areas pertaining to the management of data, data delivery, understanding protocols, is able to interpret clinical study data, and the technologies needed/used on clinical studies from start-up to completion – Roche early clinical development data management.**

Common Features

- Technical - understand data, data structure, data modelling
- Content – scientific knowledge, interpretation of data, links and connections within data

Development

Data Management



Transformation
?

Data Scientist

Data Management: *Past*



Task driven



Reactive to
the data



Reactive to
team needs



SKILL SET OF A CLINICAL DATA MANAGER

- Timeline management
- CRF/eCRF design
- Review query log
- Raise manual queries
- Review answers to manual queries
- Handle science queries
- Clarify errors
- Check of process regarding coding of terms
- Arrange for loading of electronically loaded data
- Reconcile serious adverse event between clinical data base and drug safety database
- Reconcile non-eCRF and CRF data
- Generate dose escalation snapshots
- Amend the database when necessary
- Train sites/monitors for study conduct
- Provide metrics to study management teams
- Provide data listings to vendors
- Prepare for database closure

Data Management – Perception

- At the receiving end within study management teams
- Regarded as service provider to the organization
- Easy to outsource or off-shore

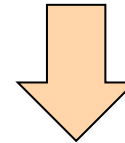


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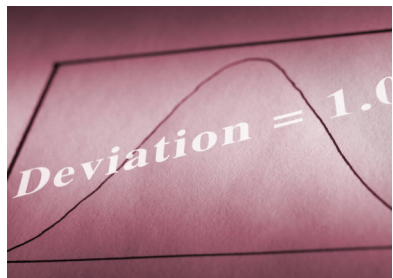
Attributes of a Clinical Data Scientist



- Clear understanding of protocols
- Oversee study milestones and what is needed for data delivery
- Conduct a risk assessment in regards of data, e.g. what needs to be clean for a therapeutic area and what data can be left as is



- Understand the basic needs of statistics and programming
- Support standards
- Understand the basics of the disease area
- Oversee external service providers
- Adapt to new technologies
- Help clinical scientist to understand the data modeling and to explore the data
- Behaviours (speaking with confidence, being heard, solution focused rather than problem presenter)



Some Examples - Protocol

- Participate in discussions during protocol writing
 - Which data points are important?
 - Are all assessments well explained?
 - Relevance of data points?
- Follow the protocol structure
 - Are synopsis and body of the text in sink?
 - Are all components of the endpoints collected and match with SoA?
- Understand primary and secondary endpoints and it's derivation(s)
 - Gain understanding from science and statistics
- Link study endpoints to captured data fields
 - Make sure most relevant data fields linked for the endpoints are identified
- Oversee eCRF and electronically loaded data
 - Where is reconciliation needed?
 - Reconciliation on panel versus analyte level

Some Examples - Behaviour

- Act as partner in study management team
- Be willing to ask and challenge
- Speak with confidence
- Make Clinical Data Management (CDM) heard
- Act as spokesperson for all CDM roles
- Outline consequences of e.g. protocol amendments on timelines
- Highlight issues and offer solutions

Transition – Clinical Data Manager to Clinical Data Scientist

- Training and workshops
 - Protocol review
 - Statistics for non-statistician
 - Basic understanding of Clinical Pharmacology
 - Life of a data point
 - Working with metrics
- Curiosity
 - Ask questions
 - Use all connections available in a study management team
 - Learn about each other

Answer to the Question

Clinical Data Scientist = Clinical Data Manager

Clinical Data Scientist = Clinical Data Manager + more content knowledge

Clinical Data Scientist = Clinical Data Manager + more content knowledge + behaviours

***Doing now what patients need
next***