END-TO-END STANDARDIZED PROCESS: DATA AND METADATA FROM PROTOCOL TO THE CSR
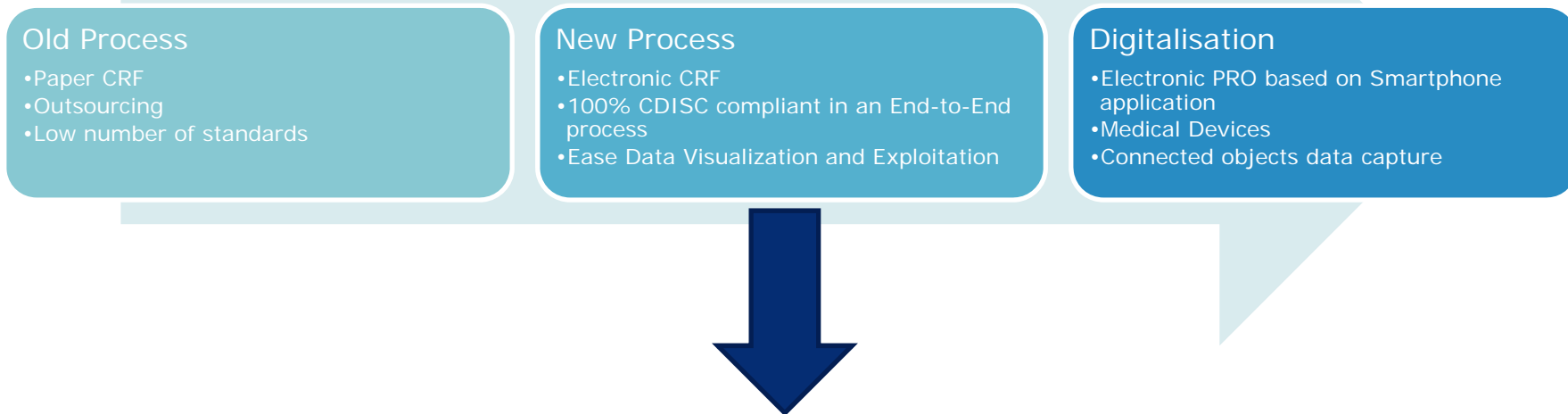
01 A VISION : ADOPT AN END-TO-END PROCESS FROM THE PROTOCOL TO THE CSR
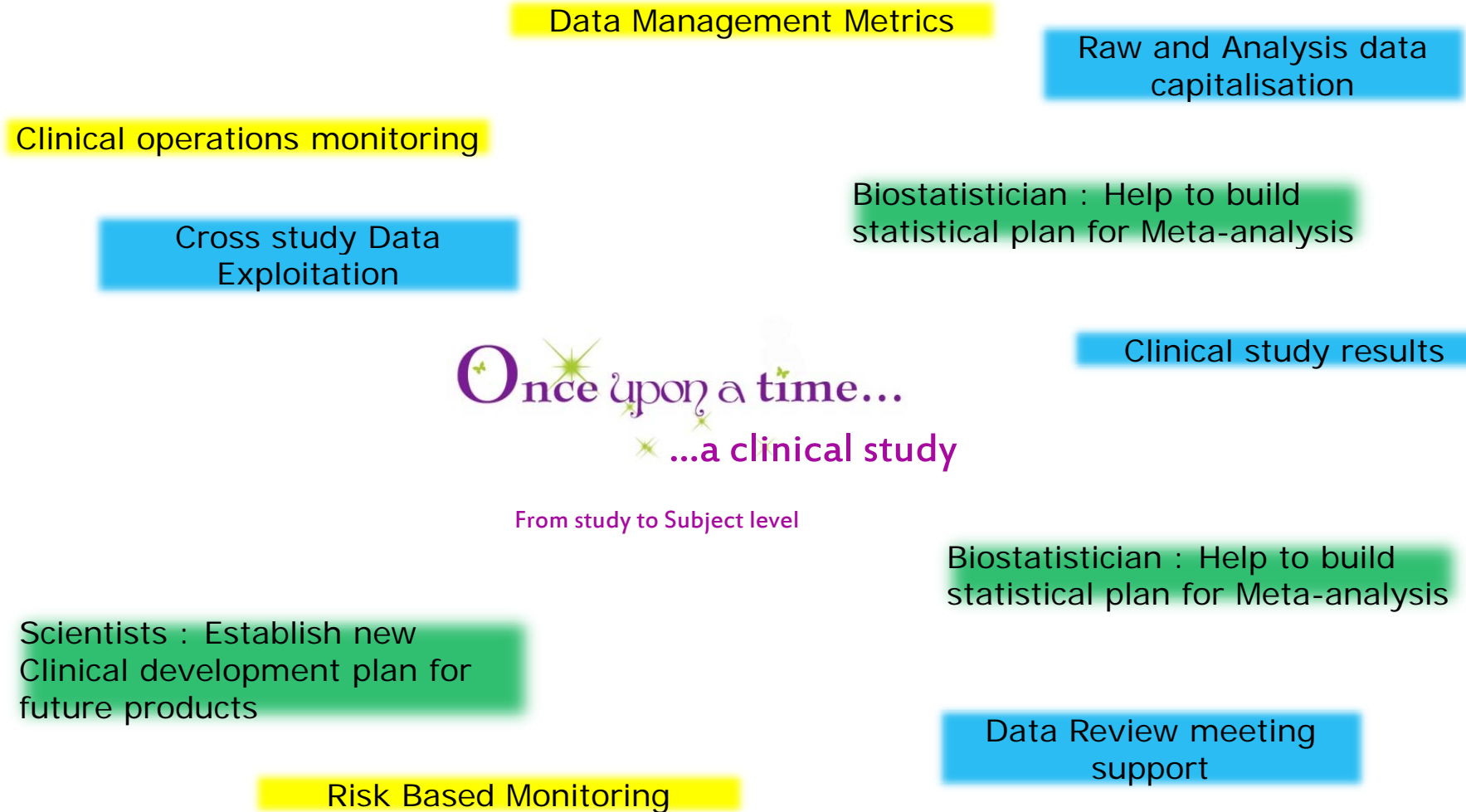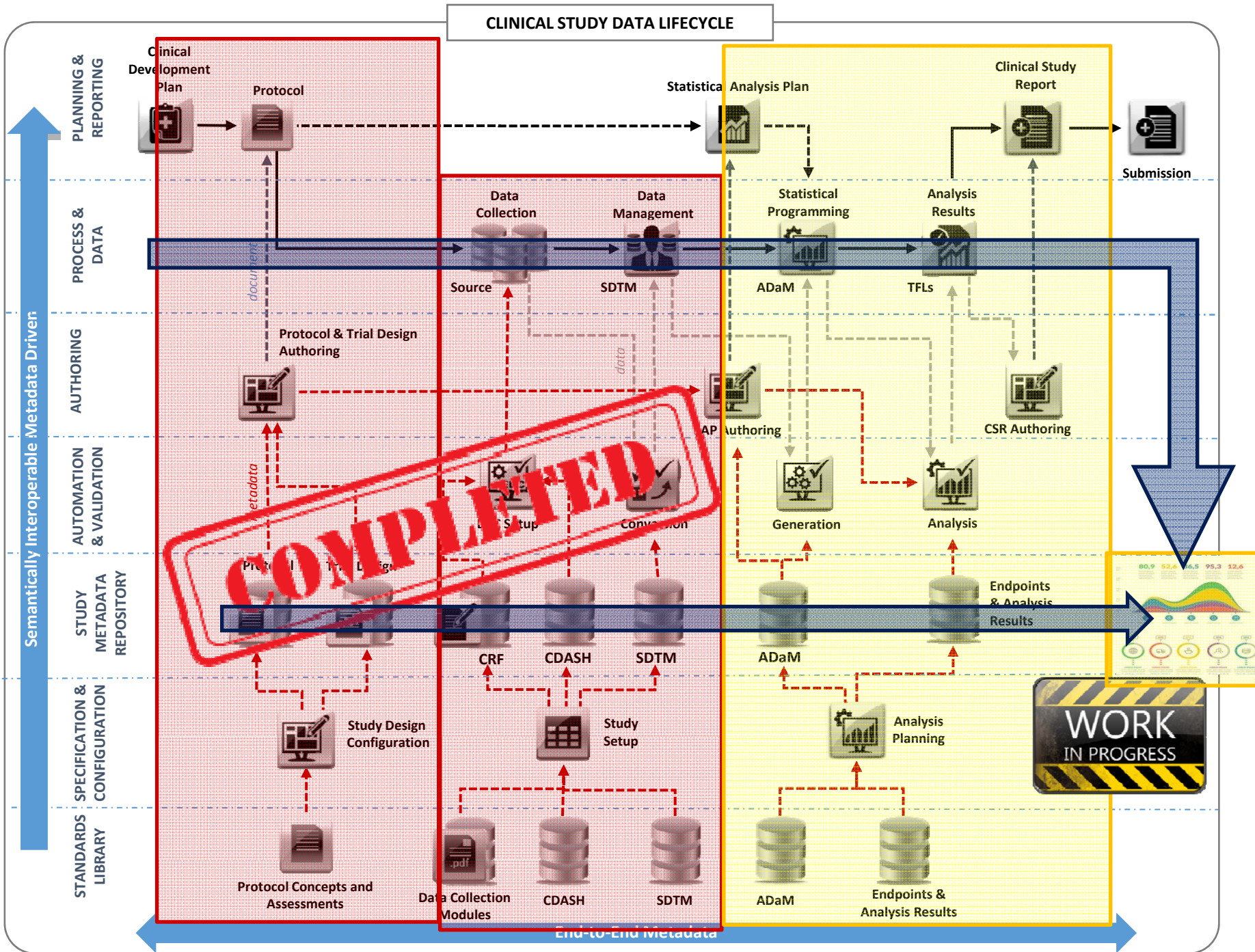
STATE OF THE ART

From Prehistoric ages to Clinical Standardised Digitalisation

Old Process
- Paper CRF
- Outsourcing
- Low number of standards

New Process
- Electronic CRF
- 100% CDISC compliant in an End-to-End process
- Ease Data Visualization and Exploitation

Digitalisation
- Electronic PRO based on Smartphone application
- Medical Devices
- Connected objects data capture

Thinking about a vision…

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…ONCE UPON A TIME…

Data Management Metrics

Raw and Analysis data capitalisation

Clinical operations monitoring

Biostatistician : Help to build statistical plan for Meta-analysis

Cross study Data Exploitation

Once upon a time…
…a clinical study

Clinical study results

From study to Subject level

Biostatistician : Help to build statistical plan for Meta-analysis

Scientists : Establish new Clinical development plan for future products

Data Review meeting support

Risk Based Monitoring

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RESEARCH

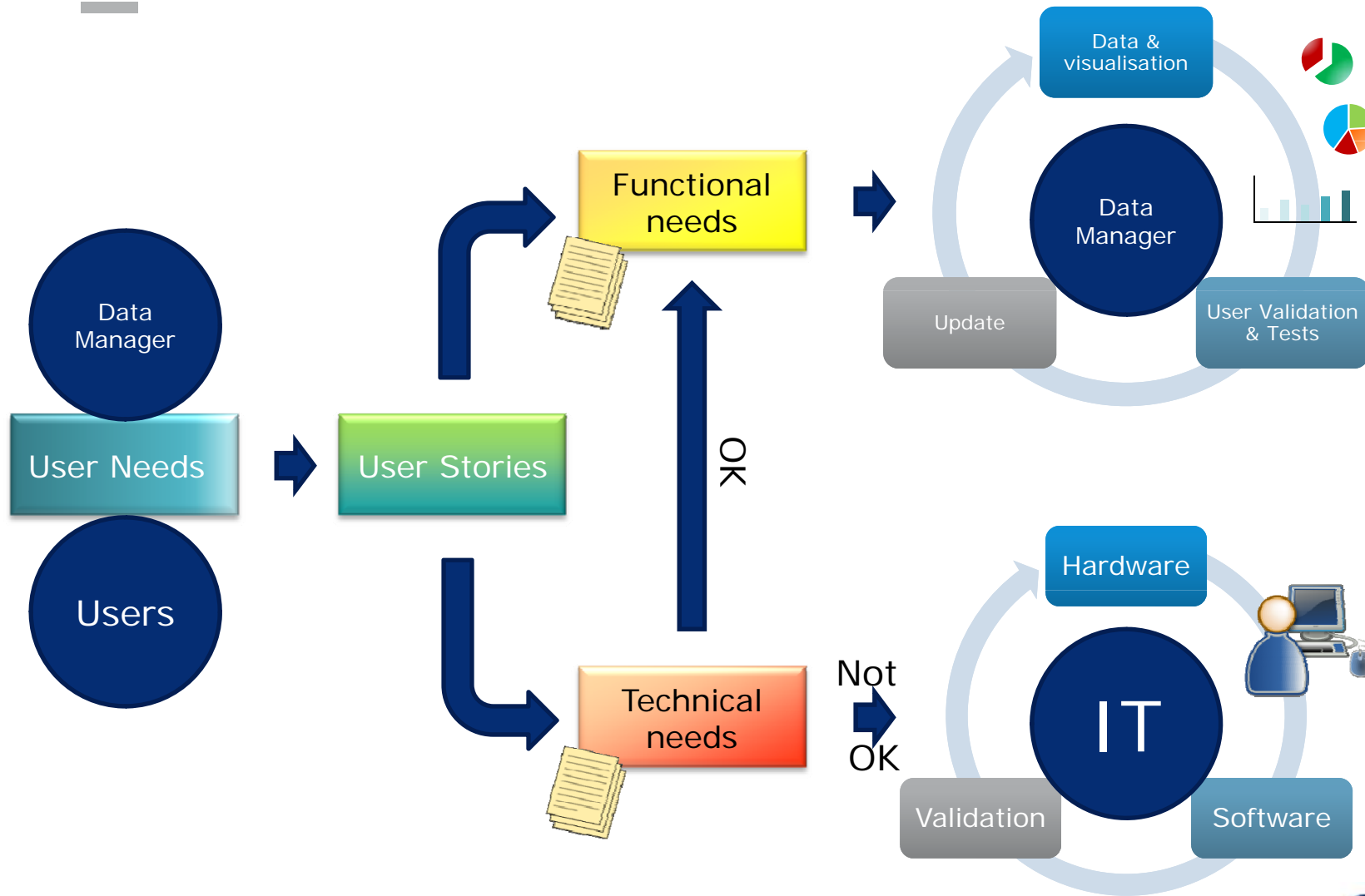**CLINICAL STUDY DATA LIFECYCLE**

DEFINING USER STORIES IS CRITICAL FOR SUCCESS

- Users Story definition
  - Common language to describe what a user does or needs to complete his job and be the support to define the list of technical needs for IT and functionalities to be designed by the Data Manager.
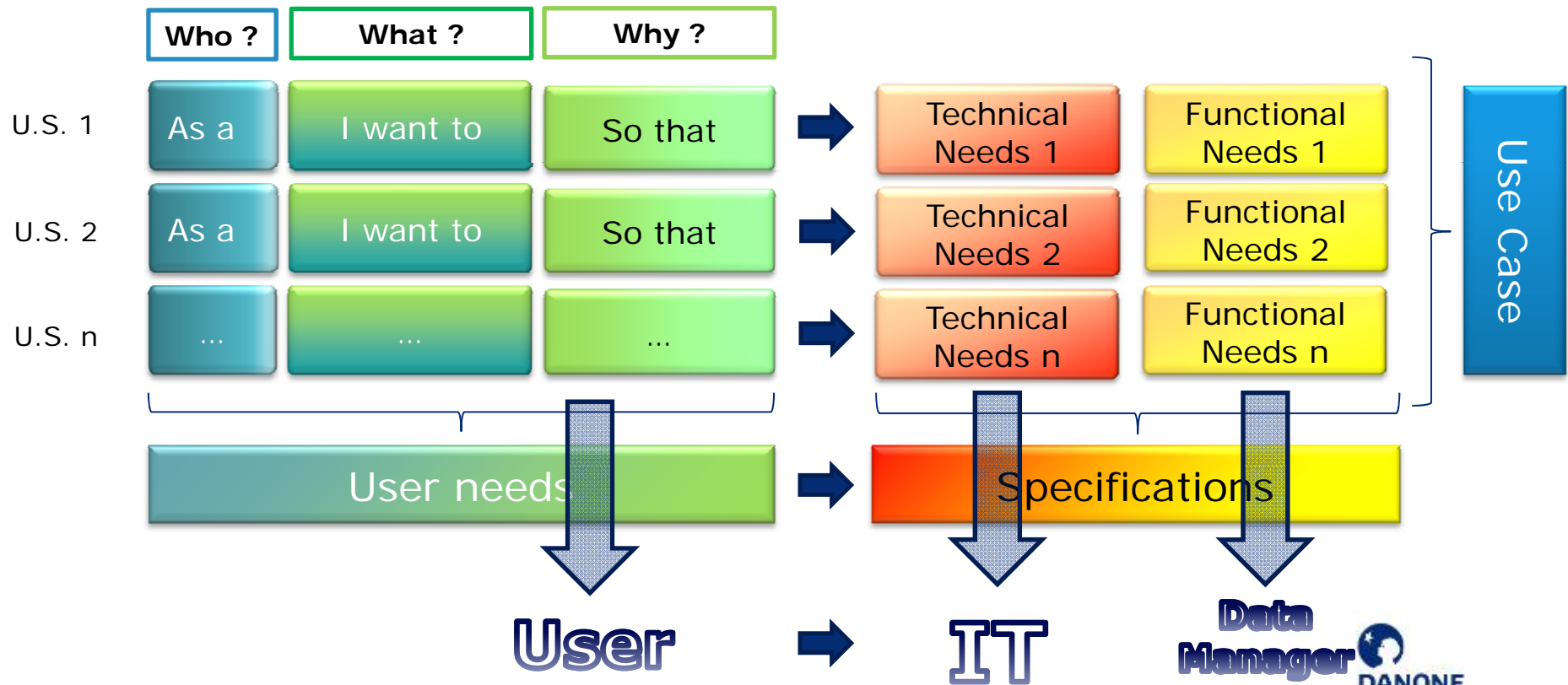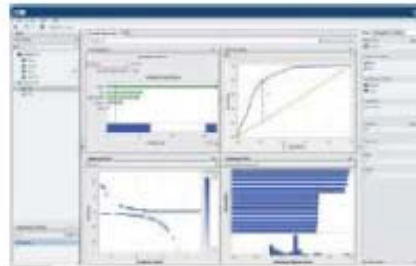
USER STORIES WORKFLOW

TECHNICAL NEEDS COVERED BY A BIG DATA CONCEPT

DASHBOARD REPORTS **VISUALIZATION** **ANALYTICS**

Data Mart   Data M...

Be Big ? No, be smart...

Management

...aging Area

Data Integrator

System 1 **System 2** **System 3** **System 4** **System**

Connectors

Streaming Data

flickr
Picasa.
TXT PDF

Unstructured Data

External Private Data

Open Data

02 ONCE UPON A TIME...
A CLINICAL STUDY

2 DEVELOPMENT PHASES

Phase 1

Phase 2

OPERATIONAL METADATA

CLINICAL METADATA

Clinical Data

CLINICAL ANALYSIS DATA

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PHASE 1 : DANONE CLINICAL DATA FLOW (DANFLOW)

Function

- CRF Metadata Repository
  - Demographics
  - Physical Exam
  - Vital Signs
  - Adverse Events
  - Con Meds.
- ODM →
- EDC
- ODM w/DATA →
- ETL
- SAS.xpt →
- Define.xml →
- SDTM →
- Data Repository

Task

| CRF Design | Data Collection and Processing | Data Mapping | Data Storage |

Tools

| Formedix ORIGINS® | OpenClinica | Medidata RAVE® | XML4Pharma SDTM ETL® | File Server |

Benefits

| EDC Independent Study doc.generation Speed up Build | Best ratio : Study Needs / Cost saving | Automate SDTM Mapping User friendly – Drag & Drop | Ease data pooling Data Visualization Data Warehousing |

| CDASH Standards | SDTM Standards |

Adopt a compatible ePRO solution

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CDISC STANDARDISATION IMPACT ON STUDY BUILD
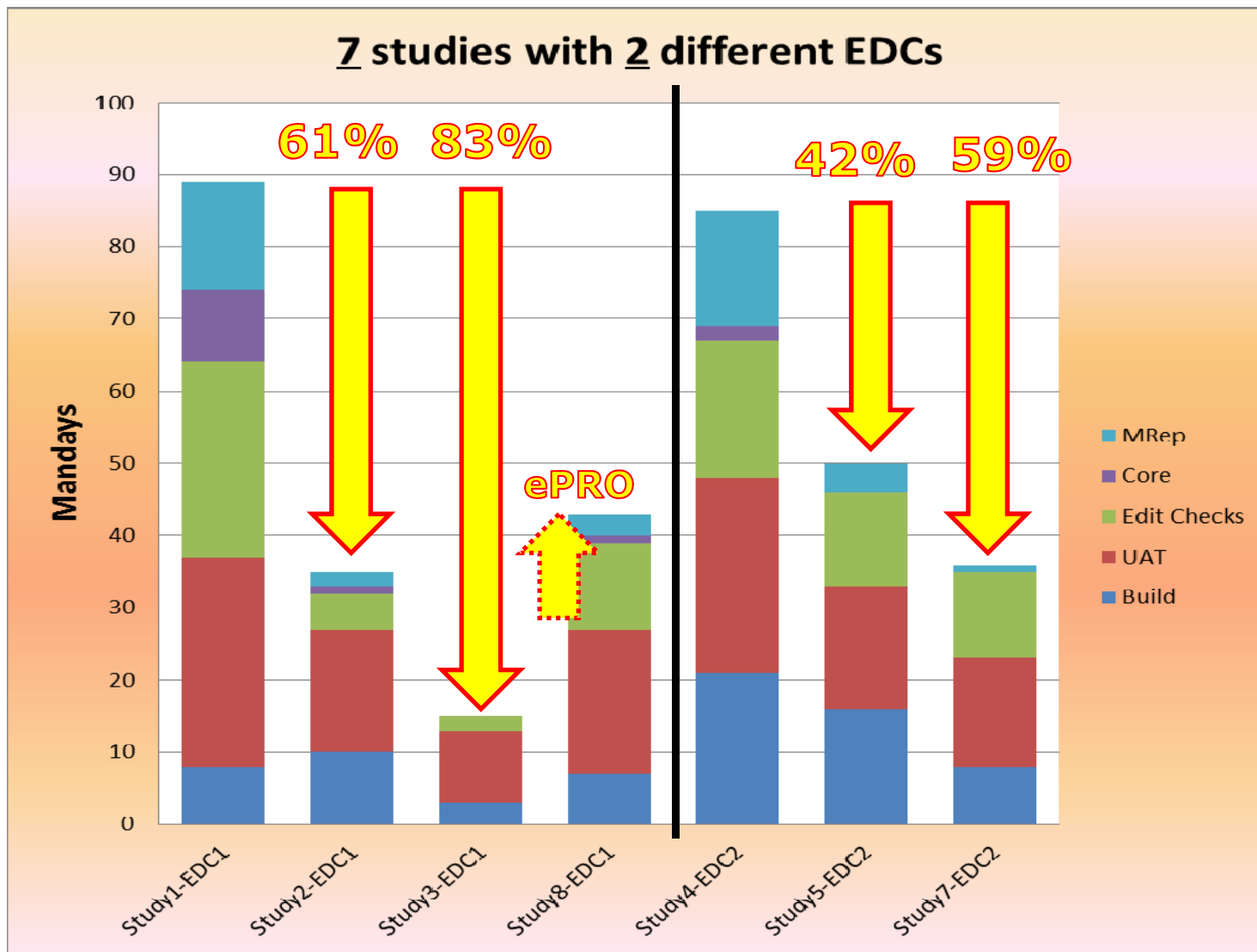
CDISC STANDARDISATION IMPACT ON DATA MAPPING
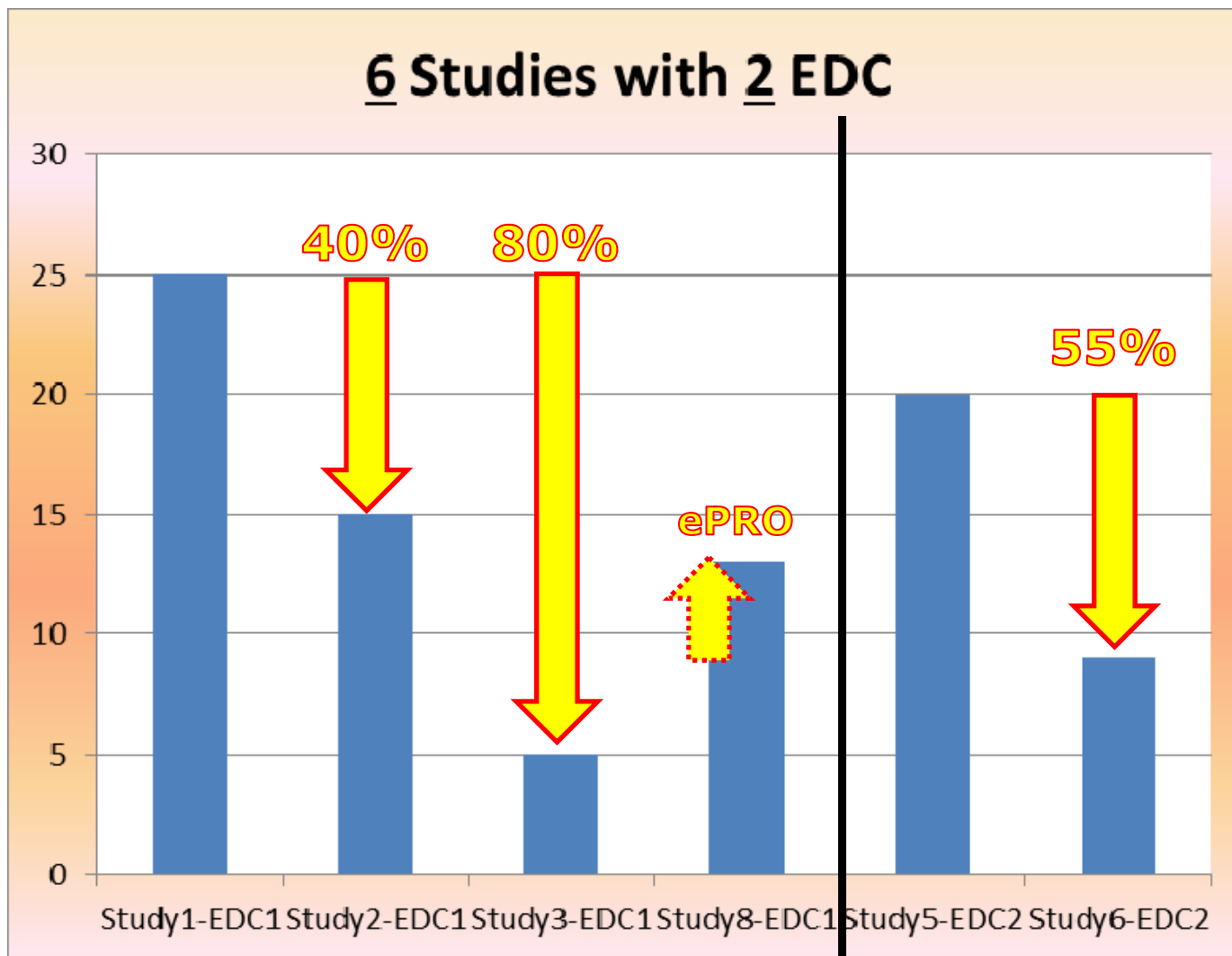
PHASE 2 : CLINICAL DATA AND METADATA (ONGOING)

Clinical DATA Pooling

Clinical Data Warehouse

CDISC

SDTM Tables
AdAM Tables

DATA Repository

DATA

Study documents

Study documents capture

Operational Metadata

Assessments
Interventions
Findings

Metadata Catalog

CDISC

Trial Design Tables

Study Metadata

Visualization

80,9   52,6   36,5   95,3   12,6

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RESEARCH
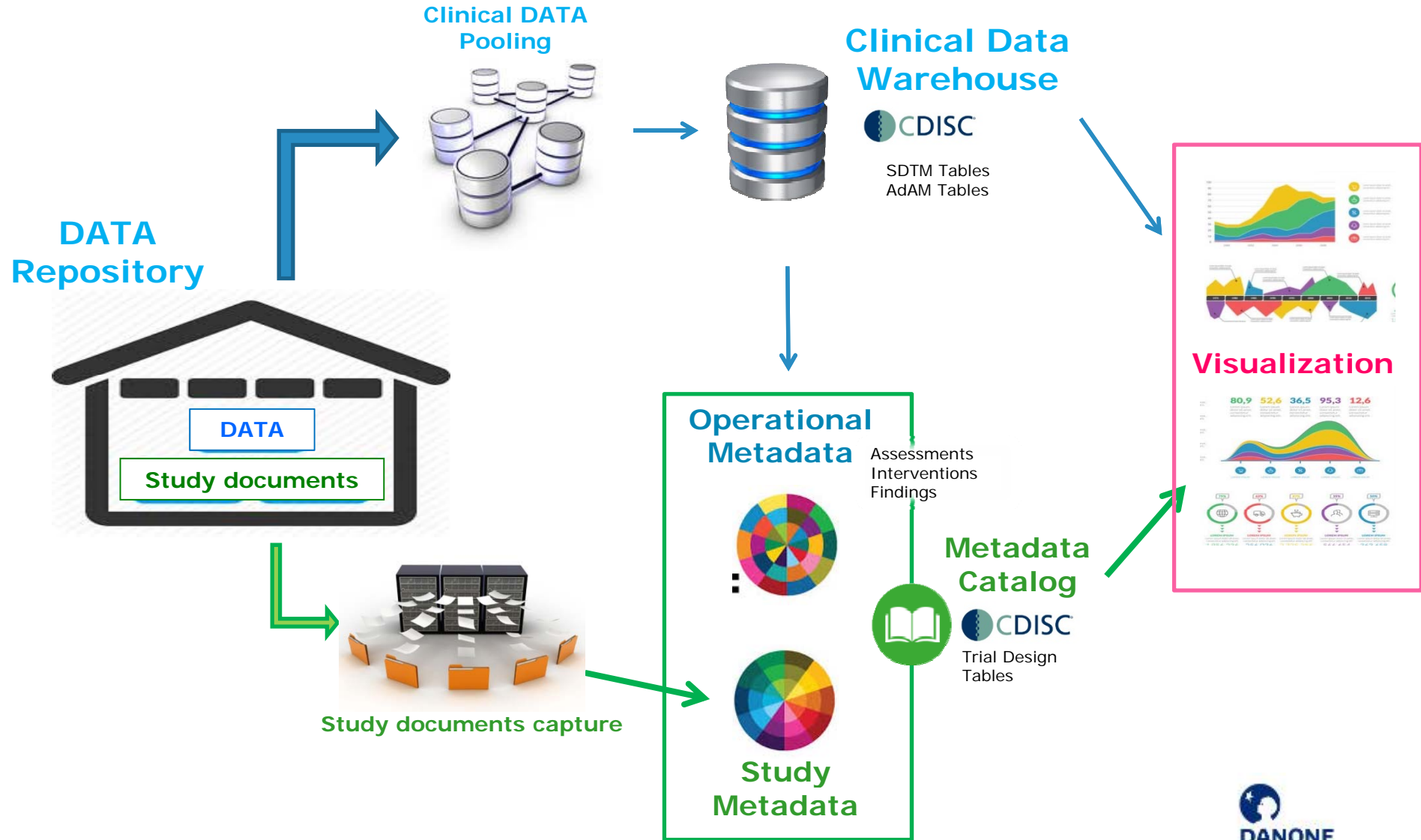
DM METRICS AND CLINICAL DASHBOARDS (ONGOING)

Data Capture on-the-fly

EDC 1 — ODM → ETL

Web Services

Data transformation

EDC 2 — ODM → ETL

Web Services

Pooled operational data

CDASH

Visualization

80,9 52,6 36,5 95,3 12,6
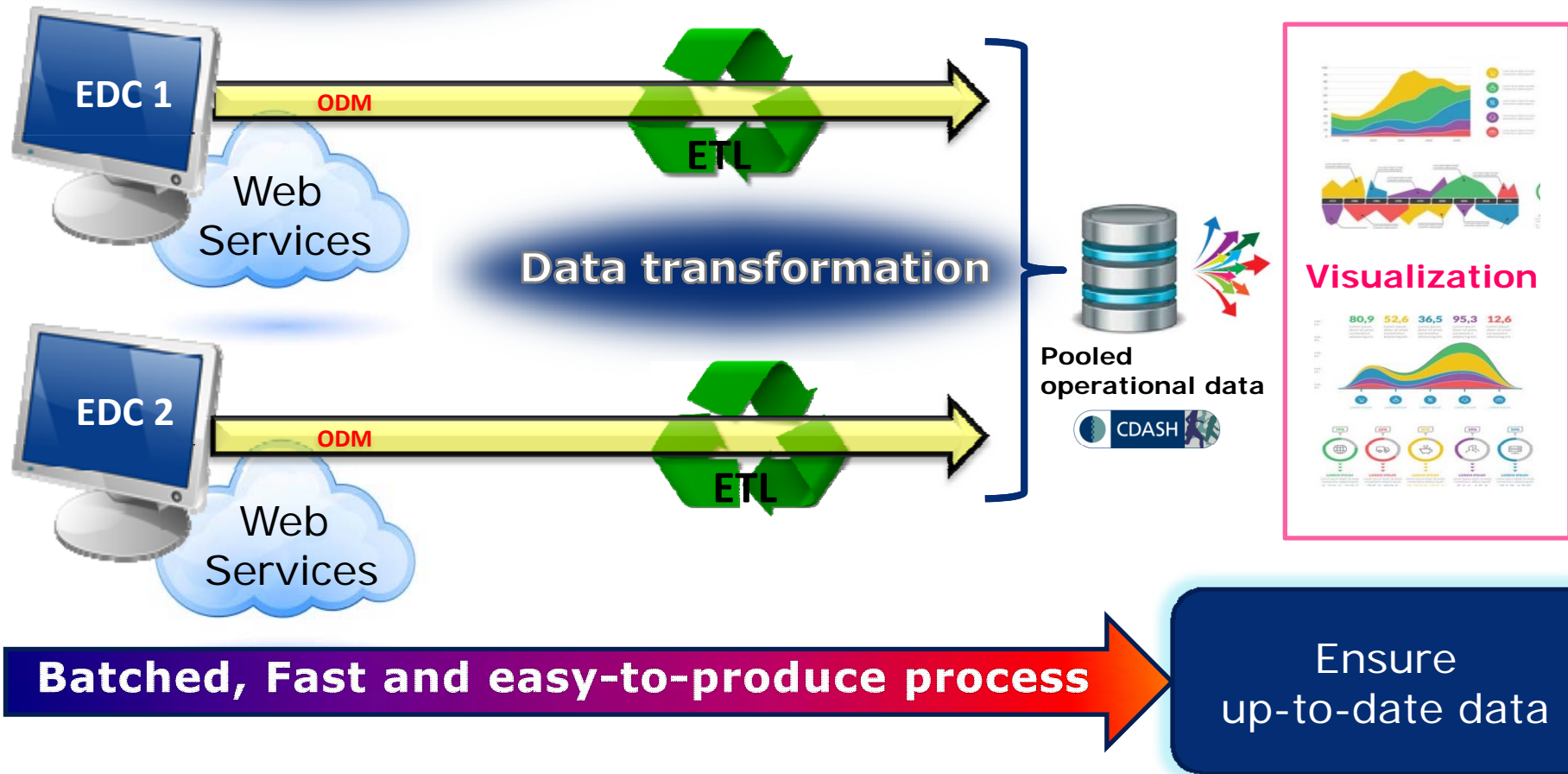
Batched, Fast and easy-to-produce process → Ensure up-to-date data

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03 DATA VISUALISATION
SOME EXAMPLES

METADATA CATALOG VISUALISATION
GLOBAL OVERVIEW
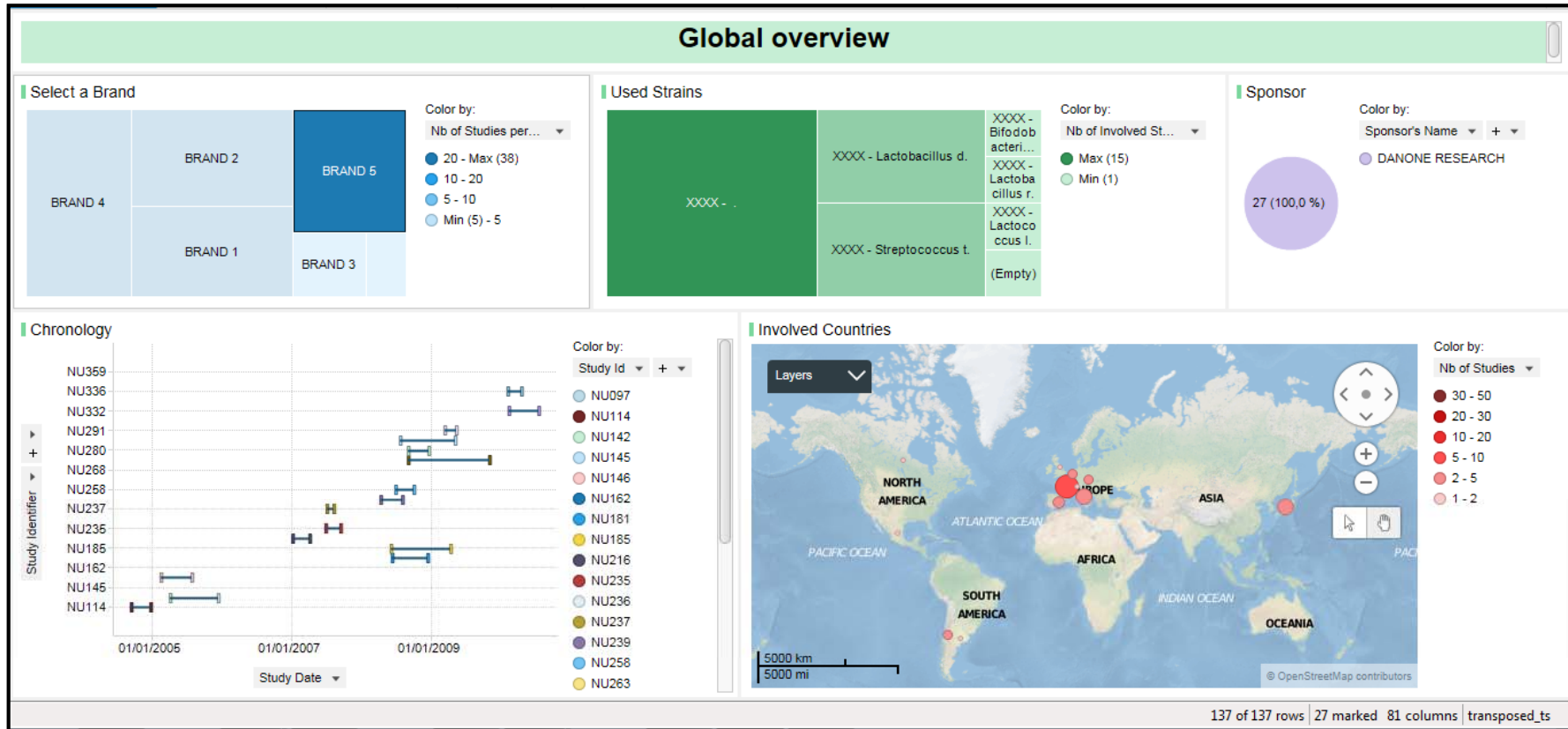
METADATA CATALOG VISUALISATION STUDY ID CARD

DATA MANAGEMENT METRICS

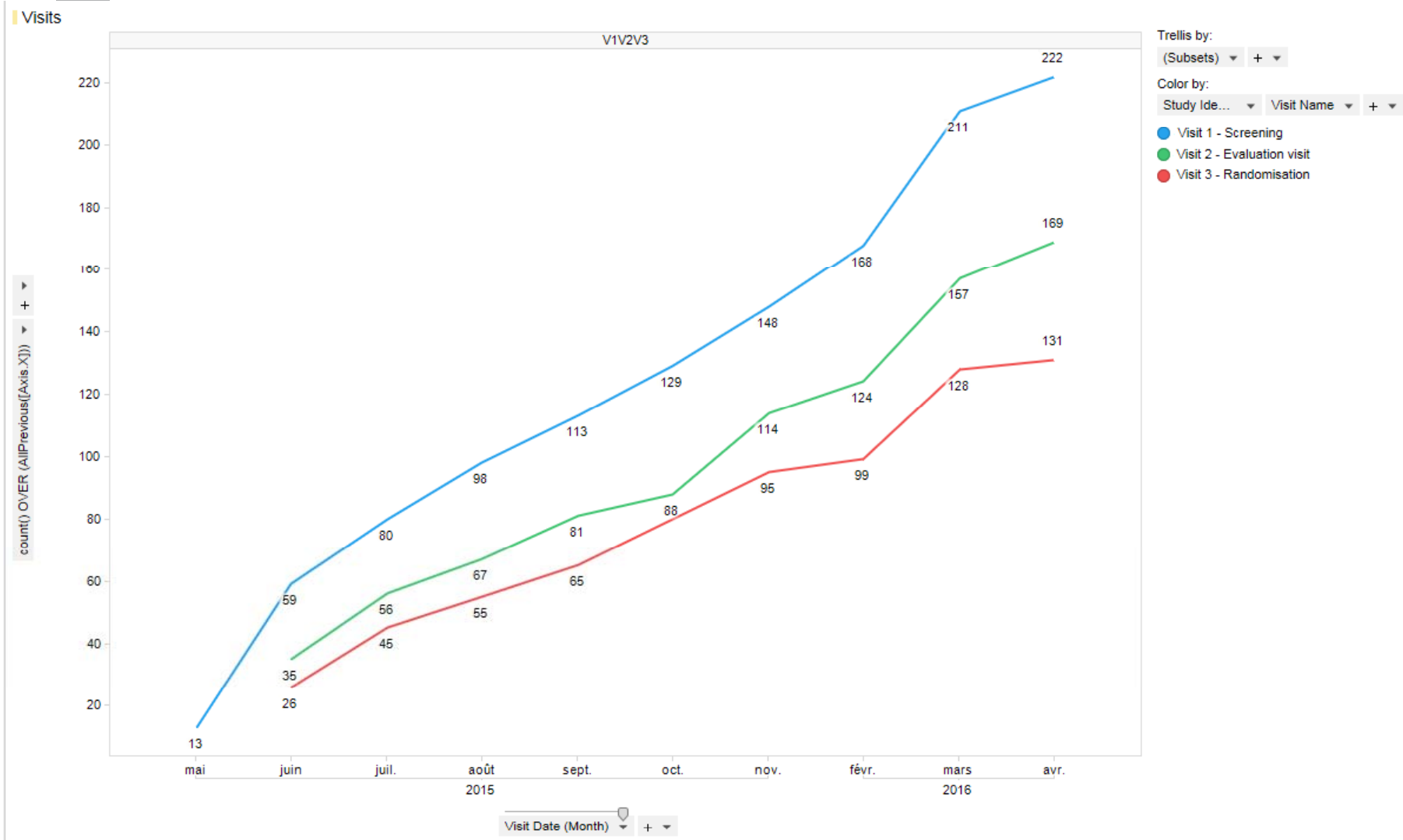# CLINICAL OPERATIONS VISUALISATION

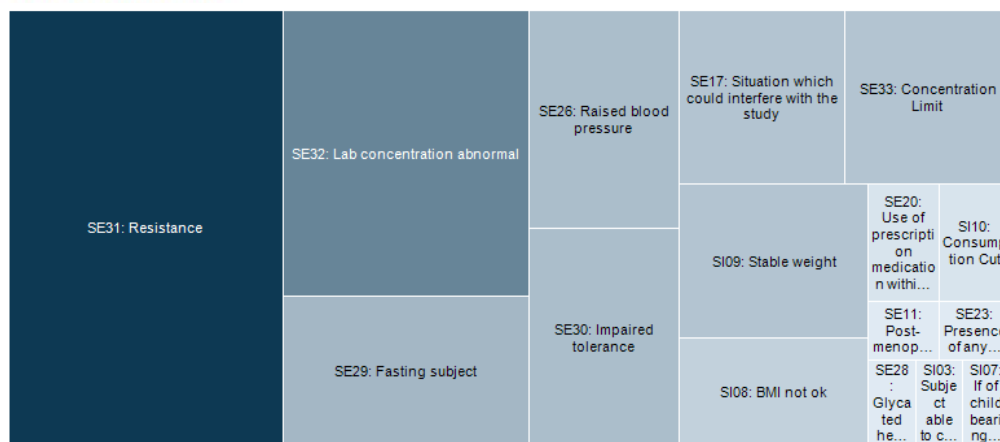# CLINICAL OPERATIONS VISUALISATION
ENROLLMENT CURVE PER VISIT – DROP OUT

CLINICAL OPERATIONS VISUALISATION
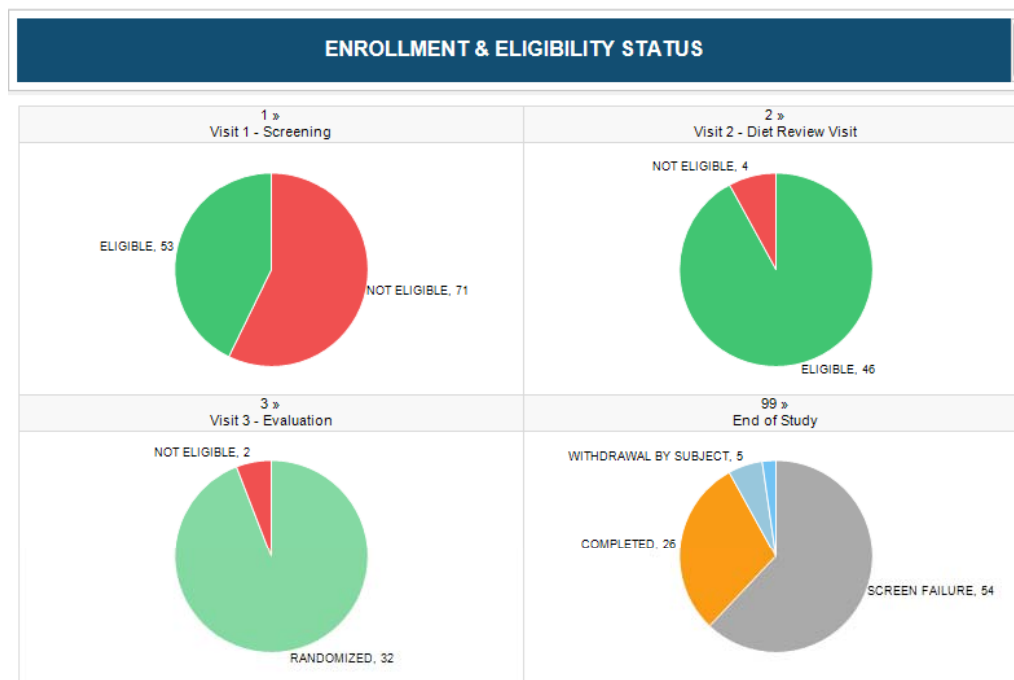
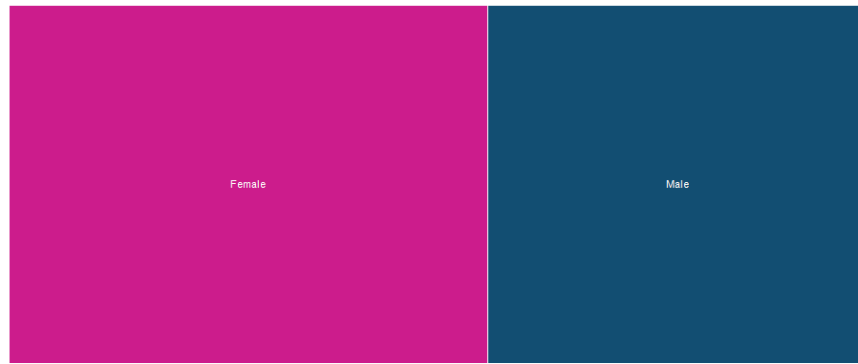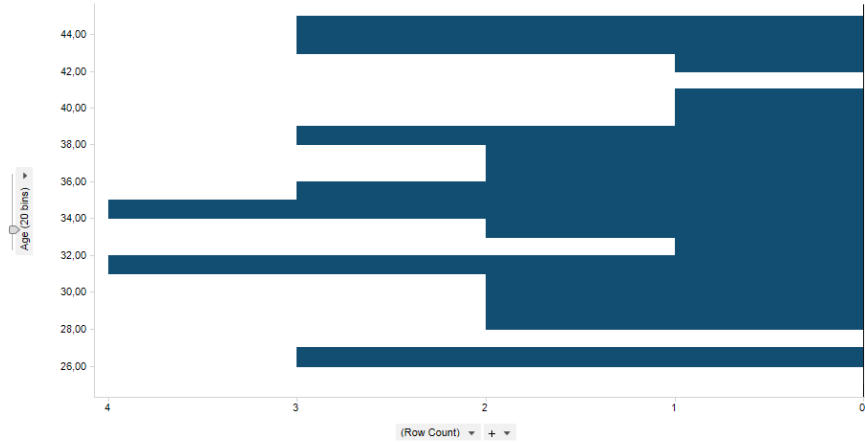# CLINICAL DATA VISUALISATION POPULATION
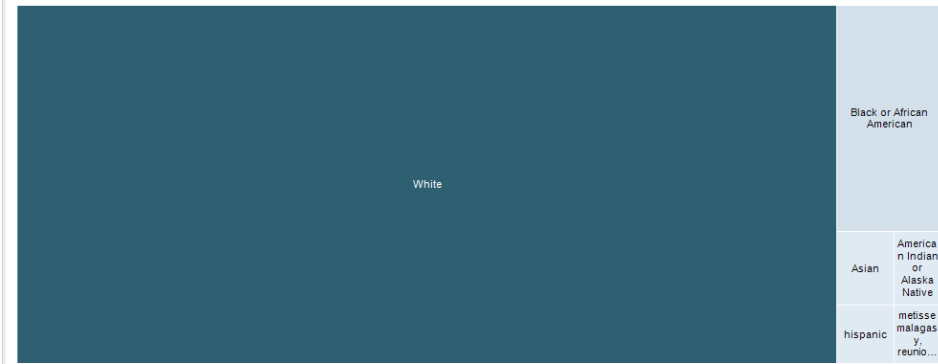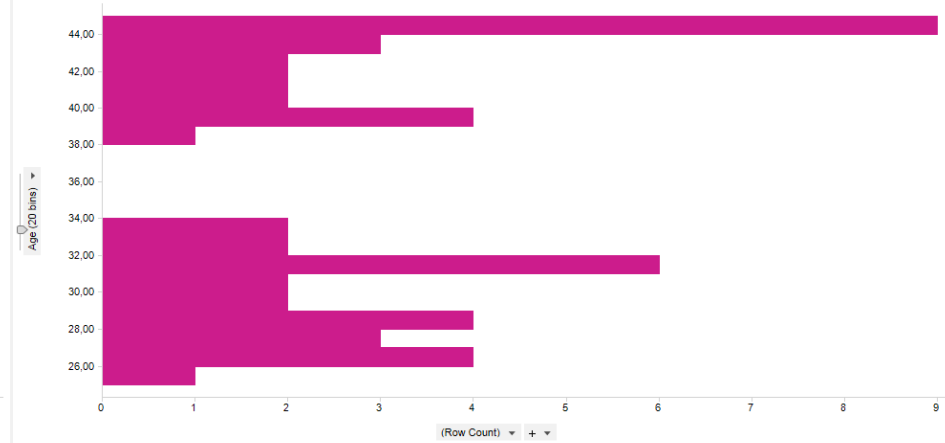
CLINICAL DATA VISUALISATION PATIENT PROFILE

DANONE NUTRICIA RESEARCH
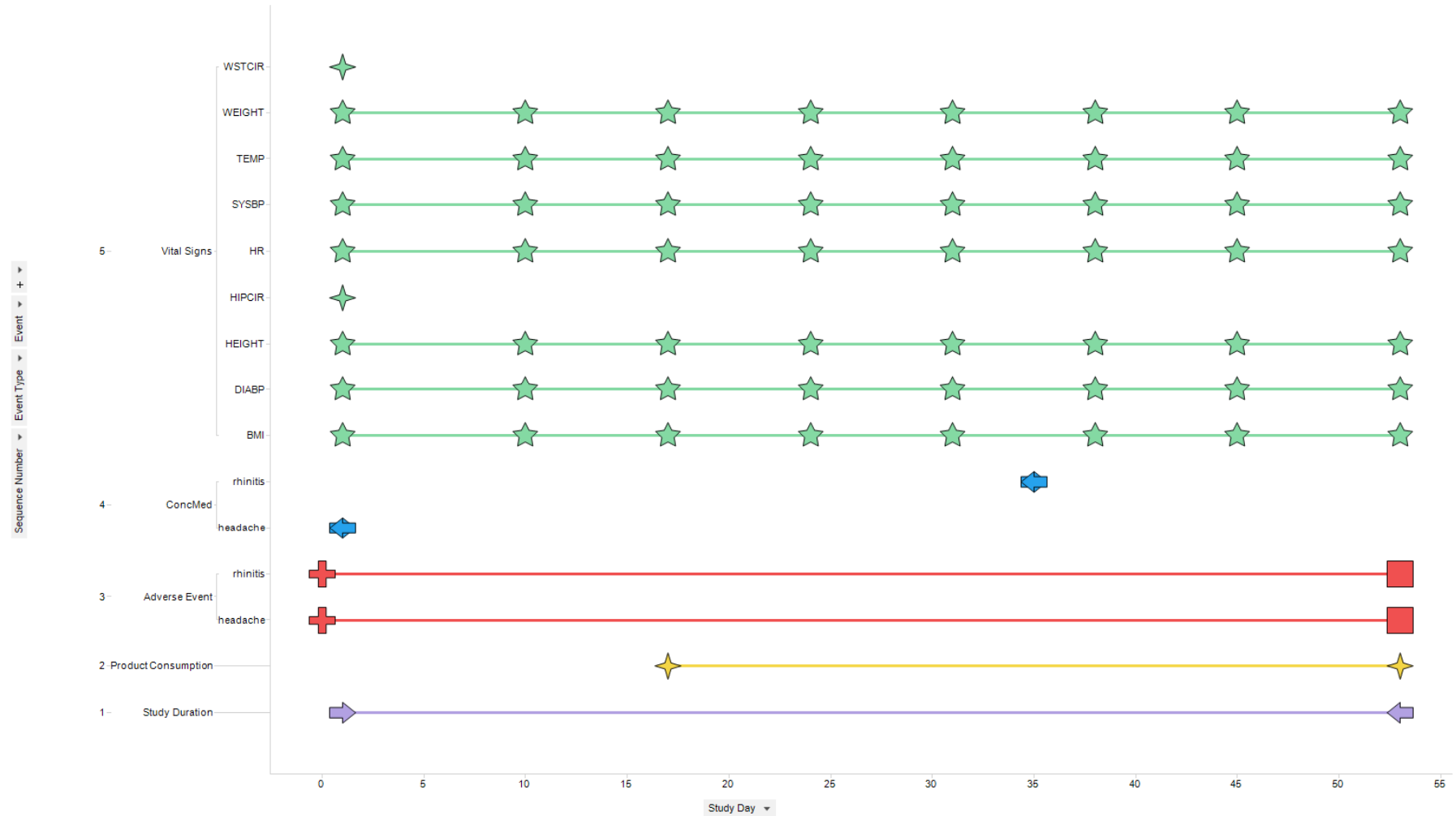
04 RETURN-ON-EXPERIENCE

...ONCE UPON A TIME...

Once upon a time...
...a clinical study

From study to Subject level

Metadata Catalog
CDISC
Trial Design Tables

Clinical Data Warehouse
CDISC
SDTM Tables
AdAM Tables

Audit Trail

EDC

CDASH

Visualization

| 80,9 | 52,6 | 36,5 | 95,3 | 12,6 |

Scientists : Establish new Clinical development plan for future products
Manager : Have an overview on KPI from all past studies
Biostatistician : Help to build statistical plan for Meta-analysis

Raw and Analysis data capitalisation
Data Review meeting support
Cross study Data Exploitation
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Clinical operations monitoring
Data Management metrics
Risk Based Monitoring

DANONE NUTRICIA RESEARCH

© March 23rd, 2017 | End-to-end standardized process: data and metadata from protocol to the csr | Gérald NEVEU

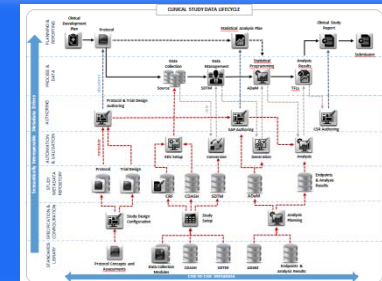# RETURN-ON-EXPERIENCE

Mandatory to use an End-to-End process integrally based on CDISC Standards for Data, Metadata and Data Management tools.

Retrieve efficiently and easily all data & information from the protocol to the CSR ensuring a continuous workflow among Clinical Core team members

Importance to use a Agile methodology based on Use Cases/User Stories to create visualisation for each business needs and exploit efficiently data & information for each user profile

THE CRAZY TEAM

Metadata Catalog
Jean Miguet

ODM Parser
Alexandre Grundstein

Metadata Collection
Marion Bonnet

Data Architect
Abderraouf Bensaber

Data Viz Designer
Simon Lebeau

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