END-TO-END DATA AND METADATA: IT'S NOT ONLY A DREAM, IT'S A REALITY
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 Tools in an End-to-End process
- Ease Data Visualization and Exploitation

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

**Data Visualisation Needs**

Support for Data Review Meeting based on Clinical Data

Study Metadata exploitation

Monitor Clinical Operations (Enrollment Curve, SDV, Data Entry, Queries, ...)

Data Management Metrics (Time to Data Entry, Number of queries per subject, Data change, ...)

More it is big, more it is important
CLINICAL STUDY DATA LIFECYCLE

STANDARD & SPECIFICATION

STUDY METADATA REPOSITORY

SEMANTICALLY INTEROPERABLE METADATA DRIVEN

AUTHORING & VALIDATION

PROCESS & DATA

PLANNING & REPORTING

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ONCE UPON A TIME...
A CLINICAL STUDY THROUGH DATA VISUALISATION
DANONE CLINICAL DATA FLOW (DANFLOW)

CRF Metadata Repository

EDC

ODM

ODM w/DATA

Data Collection and Processing

Data Mapping

ETL

Data Repository

SAS.xpt

Define.xml

SDTM

Benefits

Best ratio: Study Needs / Cost saving

Automate SDTM Mapping

User friendly – Drag & Drop

Ease data pooling

Data Visualization

Data Warehousing

CDASH Standards

SDTM Standards

CRF Design

Data Collection and Processing

Data Mapping

ETL

Data Repository

SAS.xpt

Define.xml

SDTM

Formedix ORIGINS®

OpenClinica

Medidata RAVE®

XML4Pharma SDTM ETL®

File Server

EDC Independent Study doc. generation

Speed up Build

CRF Design

Data Collection and Processing

Data Mapping

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CDASH Standards

SDTM Standards

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Adopt a compatible ePRO solution
DATA PREPARATION FOR VISUALISATION

DATA Repository

Clinical DATA Pooling

Clinical Data Warehouse

SDTM Tables
AdAM Tables

Visualization

Operational Metadata
Assessments
Interventions
Findings

Metadata Catalog
CDISC

Trial Design Tables

Study Metadata

Study documents capture
DM METRICS AND CLINICAL DASHBOARDS (ONGOING)

Data Capture on-the-fly

Data transformation

Batched, Fast and easy-to-produce process

Ensure up-to-date data

EDC

Web Services

ODM

ETL

Visualization

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DATA VISUALISATION
SOME EXAMPLES
Global overview

- Select a Brand:
  - BRAND 4
  - BRAND 5
  - BRAND 1
  - BRAND 2

- Used Strains:
  - **XXXX - Lactobacillus g:**
    - 20 - Max (36)
    - 10 - 20
    - 5 - 10
    - Min (5) - 5
  - **XXXX - Lactobacillus c:**
    - Max (15)
  - **XXXX - Streptococcus t:**
    - Min (1)

- Sponsor:
  - Sponsor’s Name
  - DANONE RESEARCH
  - 27 (100.0 %)

- Chronology:
  - NU359, NU358, NU332, NU261, NU250, NU258, NU257, NU256, NU162, NU146, NU114
  - Study Dates:
    - 01/01/2006
    - 01/01/2007
    - 01/01/2009

- Involved Countries:
  - Map showing countries with colored dots indicating number of studies:
    - North America
    - South America
    - Asia

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### Protocol Description

**Brand:** BRAND 5  
**Study name:** ATTACK SAFETY  
**Study Code(s):** NU360  
**Study title:** A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, PARALLEL STUDY TO EVALUATE THE SAFETY OF EXCESSIVE CONSUMPTION OF PLANT STEROID-ENRICHED FERMENTED DAIRY PRODUCT OVER A 4-WEEK PERIOD IN JAPANESE HEALTH

**Clinical Study Sponsor:** DANONE RESEARCH  
**Study Type:** INTERVENTIONAL  
**1 planned Country}(ies):** JAPAN  
**Investigational Sites:** INDICATION 2

### Data Content

<table>
<thead>
<tr>
<th>Category</th>
<th>Parameter Name</th>
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<tbody>
<tr>
<td>Adverse Event</td>
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<tr>
<td>Demographics</td>
<td>Date/Time of Birth</td>
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<tr>
<td>Demographics</td>
<td>Race</td>
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<td>Aspartate Aminotransferase / SGOT</td>
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<tr>
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<td>Albumin / Microalbumin</td>
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<td>Laboratory Test</td>
<td>Creatine Kinase / CRP</td>
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<td>Blood Urea Nitrogen</td>
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<tr>
<td>Laboratory Test</td>
<td>Leucocytes / Leukocytes</td>
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<td>Laboratory Test</td>
<td>Desipramine</td>
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### Study Design

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<th>1-Wash-Out</th>
<th>2-Control Product</th>
<th>2-Test Product</th>
<th>3-Follow-up</th>
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</thead>
<tbody>
<tr>
<td>Control Product - Place</td>
<td>Follow-up</td>
<td>Test Product</td>
<td>Wash-Out</td>
<td></td>
</tr>
</tbody>
</table>

### Study Documentation

- **Document Name:** CSR  
  - Hyperlink: Click here to access
- **Document Name:** Budget  
  - Hyperlink: Click here to access
- **Document Name:** Study Global Planning  
  - Hyperlink: Click here to access
- **Document Name:** Lock Authorization Form  
  - Hyperlink: Click here to access
- **Document Name:** Final Protocol  
  - Hyperlink: Click here to access

793 of 793 rows | No marking | 4 columns | frontend.js
CLINICAL DATA VISUALISATION

SUBJECT RECRUITMENT PER WEEK

Number of subjects by Visit 1

Recruited subjects per week
04 RETURN-ON-EXPERIENCE
USE CASES & BENEFITS

Metadata Catalog
- CDISC
- Trial Design Tables

Clinical Data Warehouse
- CDISC
- SDTM Tables
- AdAM Tables

Visualization

EDC
- CDASH

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
Clinical study results

Clinical operations monitoring
Data Management metrics
Risk Based Monitoring

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