



## IMPLÉMENTATION ET GESTION DE MÉTADONNÉES D'ÉTUDES



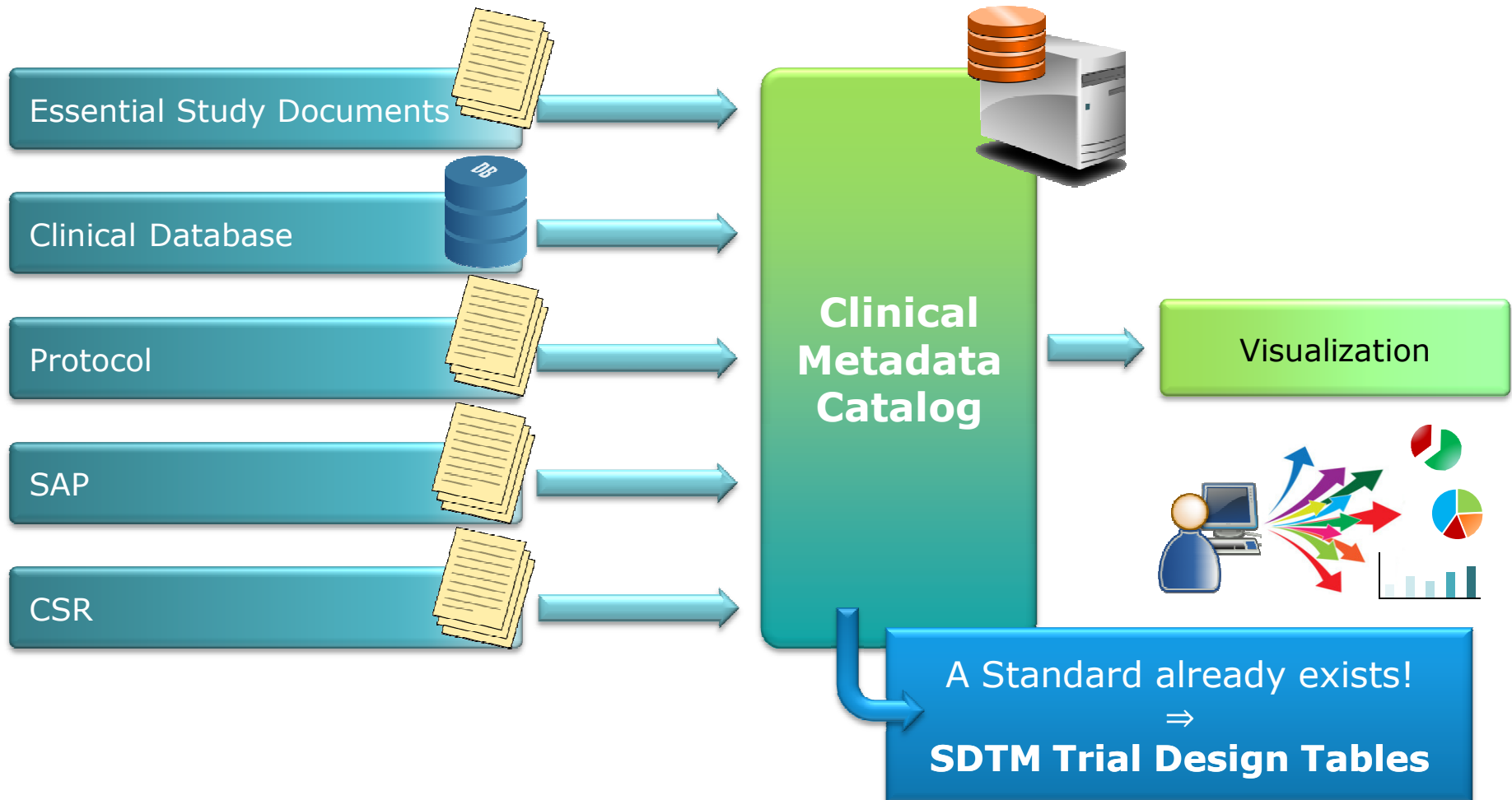
# CONTEXT

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- Etat des lieux
  - Clinical study history is not easily exploitable
  - Strong Business Need to make this information available  
→ **at the right time, to the right people**

↳ Objective – Create a Clinical Metadata Catalogue

# CLINICAL METADATA CATALOG



# TRIAL DESIGN TABLES, WHAT IS IT?

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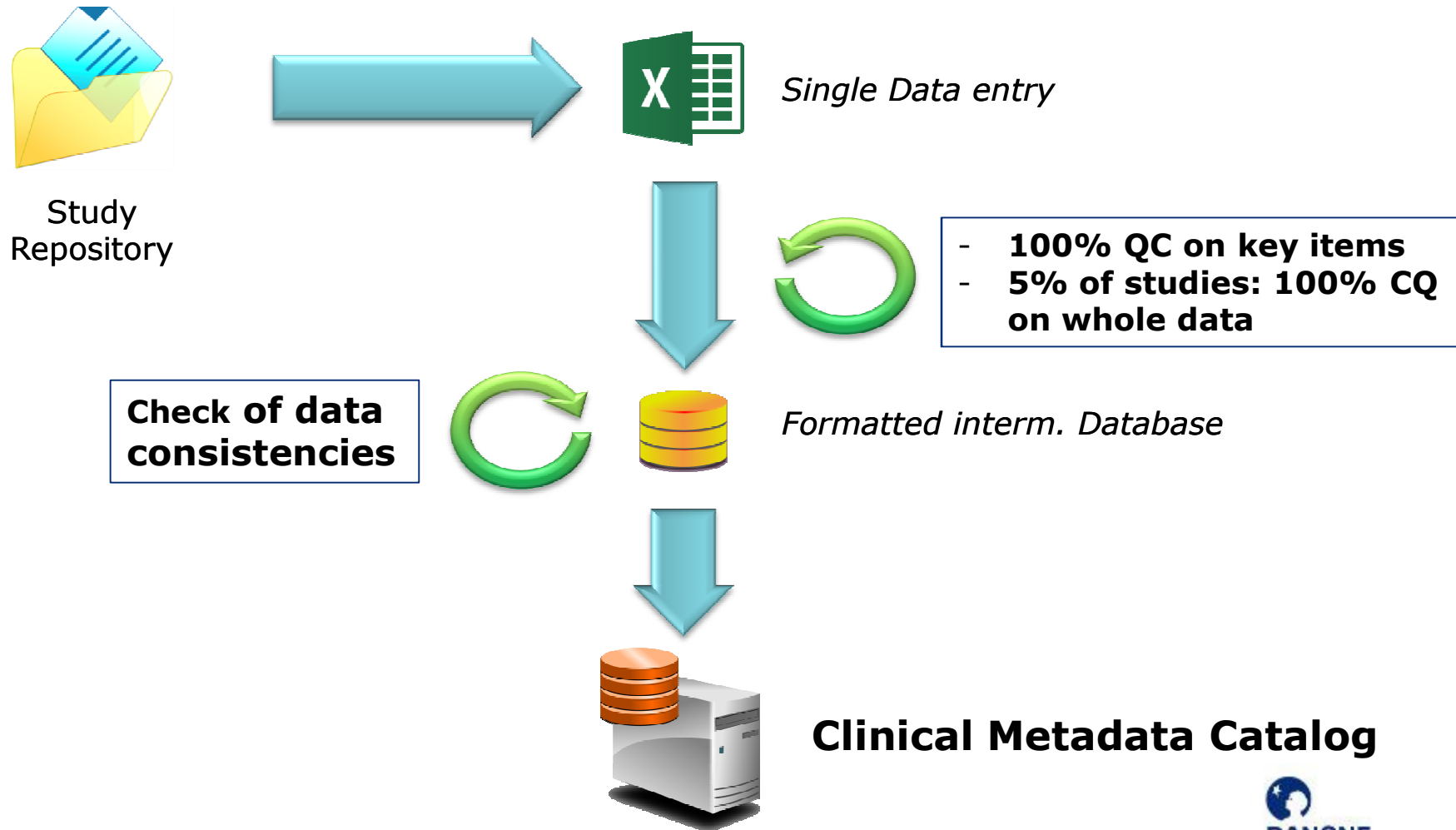
- Experimental design:
  - TA – Trial Arms
  - TE – Trial Elements
- Schedule For Assessments
  - TV – Trial Visits
  - TD – Trial Disease Assessments
- Trial Summary And Eligibility
  - TS – Trial Summary
  - TI – Trial Inclusion/Exclusion Criteria

# TRIAL DESIGN TABLES, WHY?

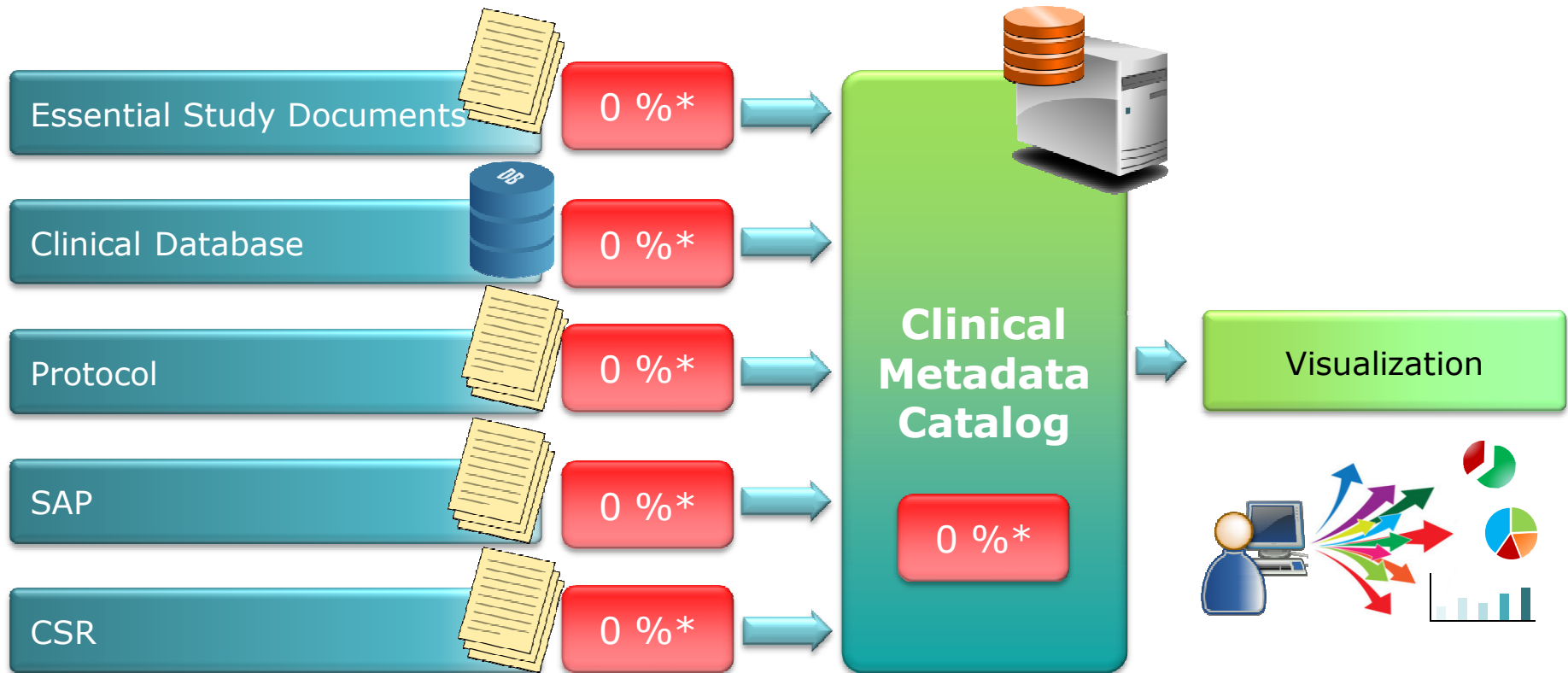
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- Cover most of our requirements
- CDISC standards already implemented at DM / stat levels
- Adaptations needed
  - Examples:
    - Domain TD – Trial Disease, not implemented
    - Domain TP - Trial Product, to collect information about the product
    - Drill down till the unitary data level

# OLD STUDIES – PROCESS



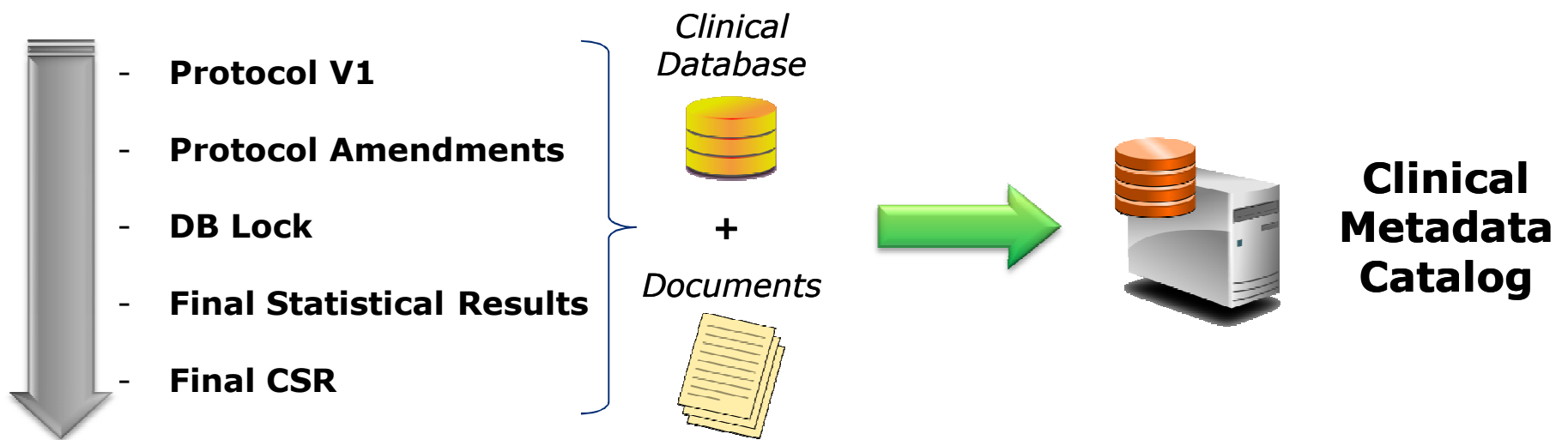
# OLD STUDIES – AUTOMATION



*\*: Percent automated based on numbers of average number of records per study*

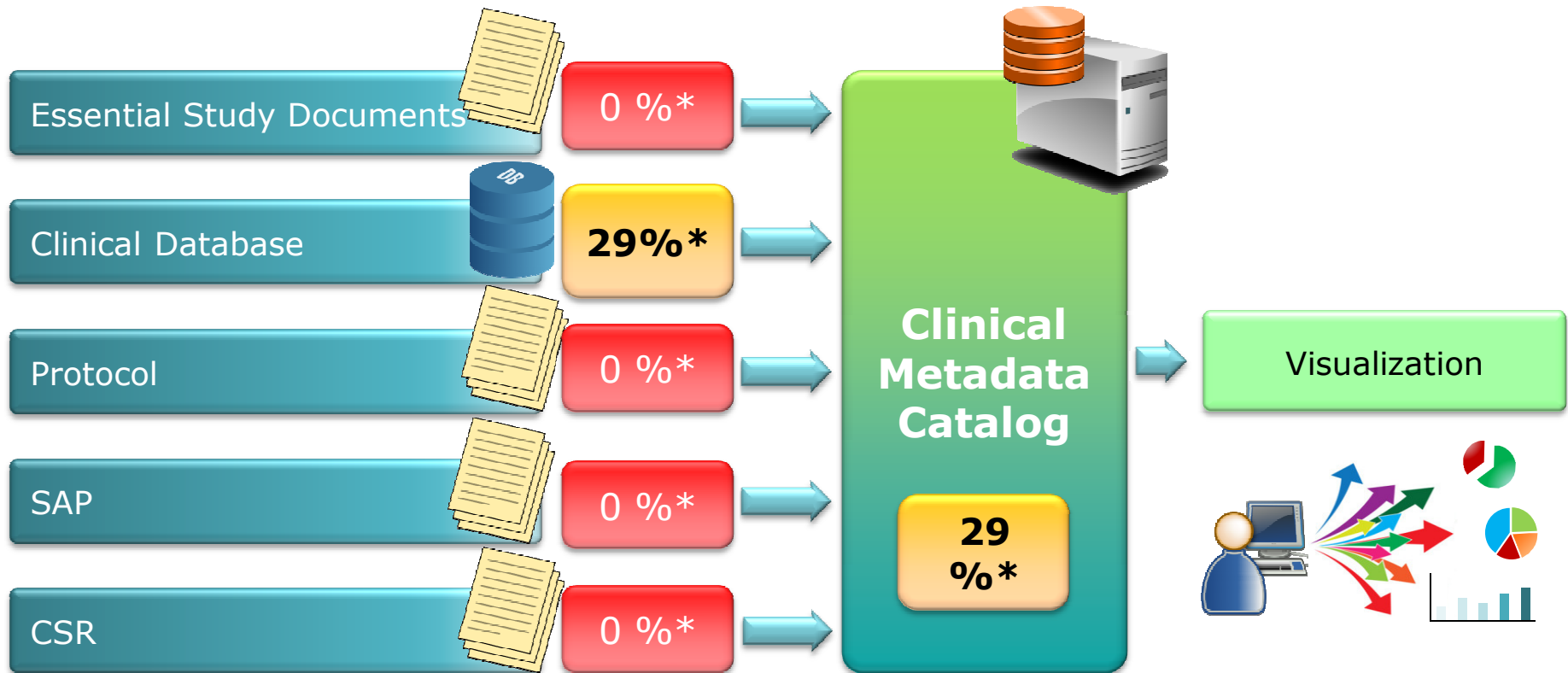
# CURRENT STUDIES – PROCESS

## Study Milestones:



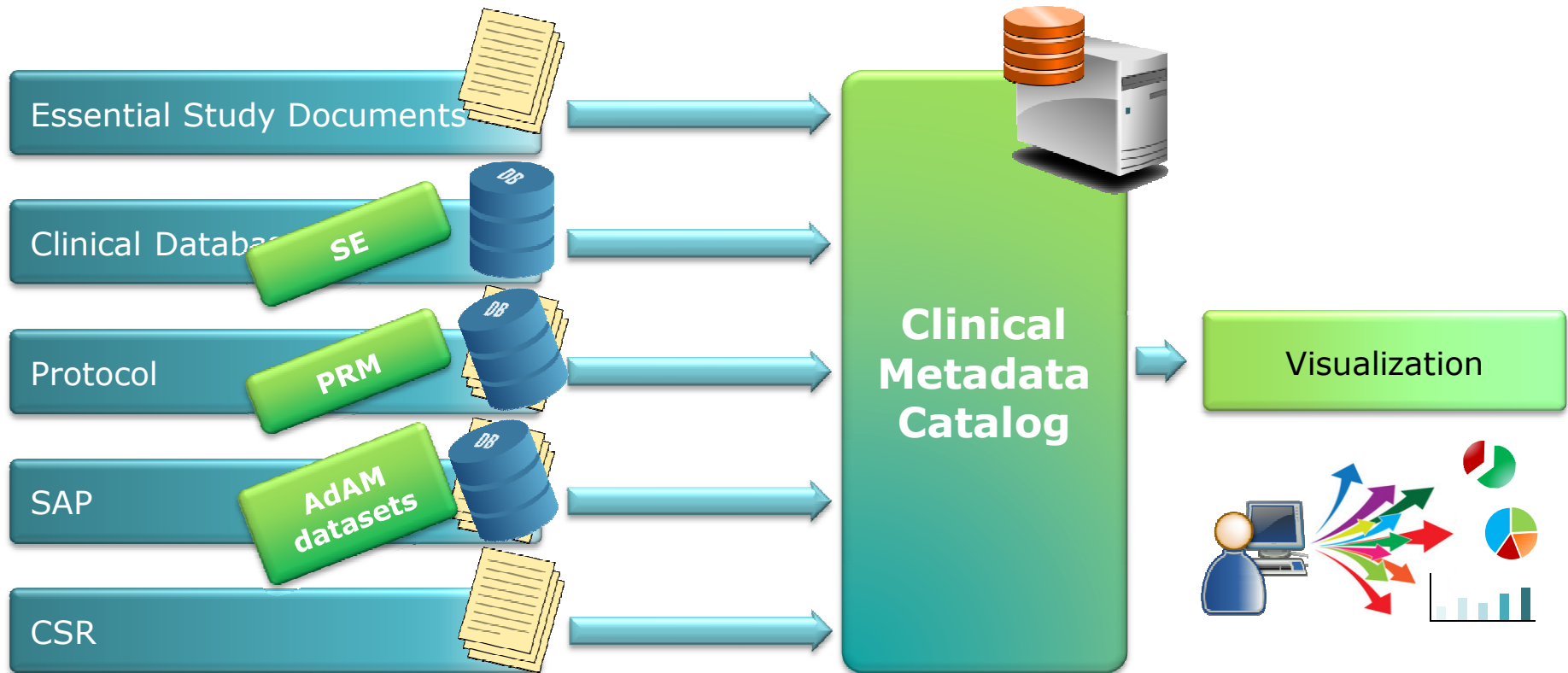


# CURRENT STUDIES – AUTOMATION



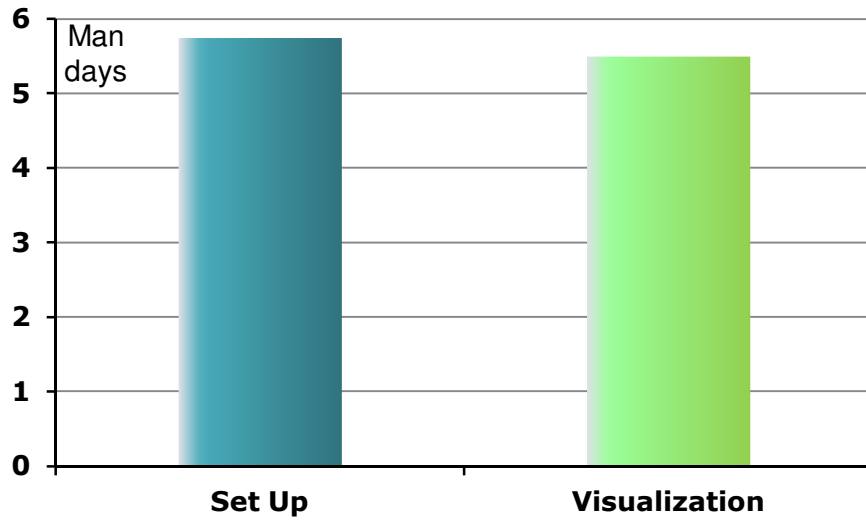
**\***: Percent automated based on numbers of average number of records per study

# AUTOMATION – FUTURE PERSPECTIVES



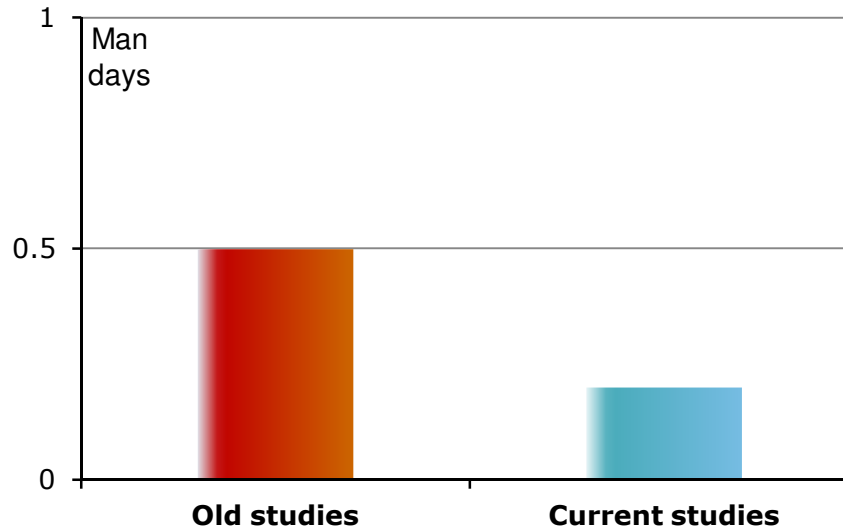
**Objective:** Percent. automation of Clinical Metadata Catalog  $\approx$  **90 %**

# IMPLEMENTATION RESOURCES

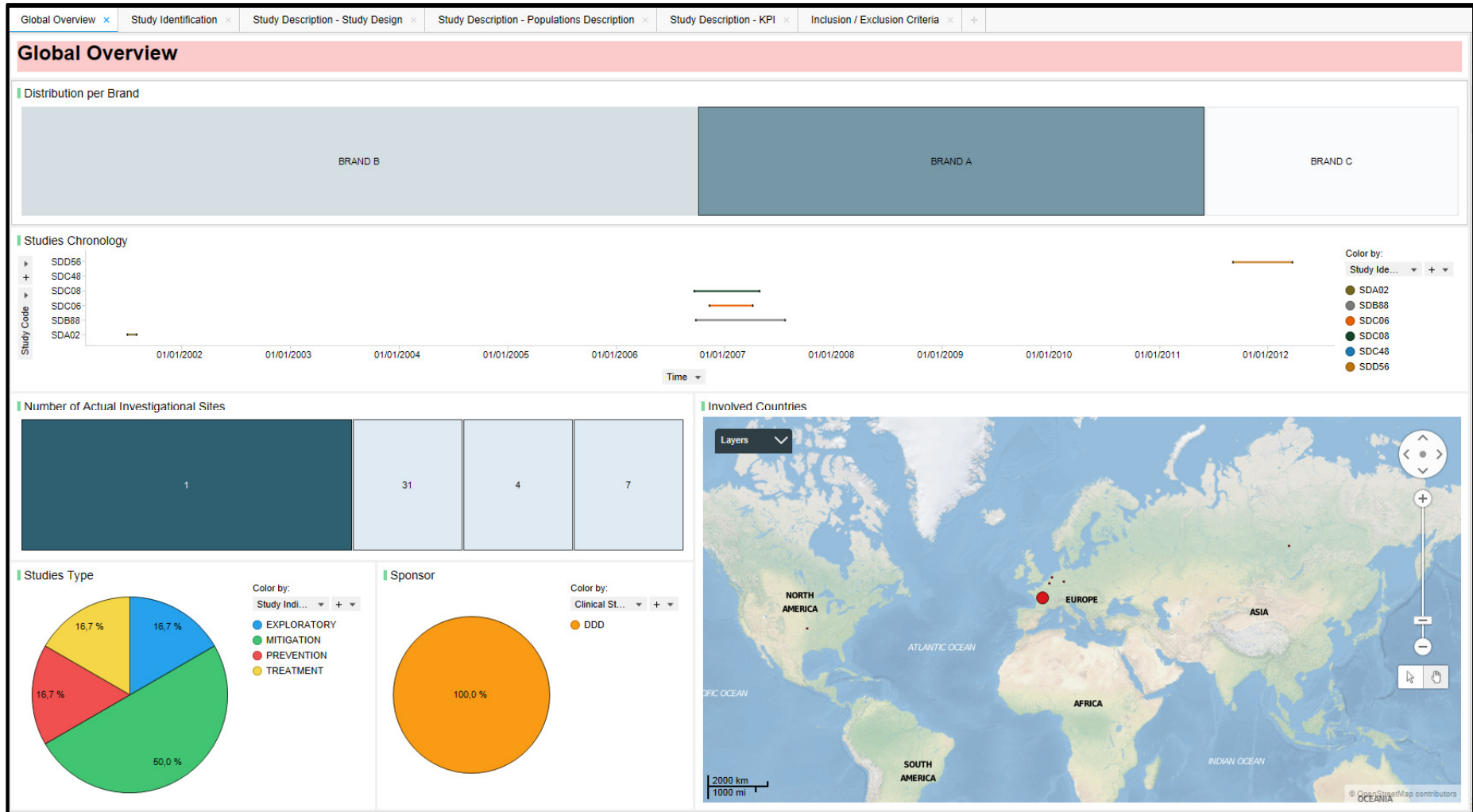


Process

Implementation



# VISUALIZATION – SOME EXAMPLES...



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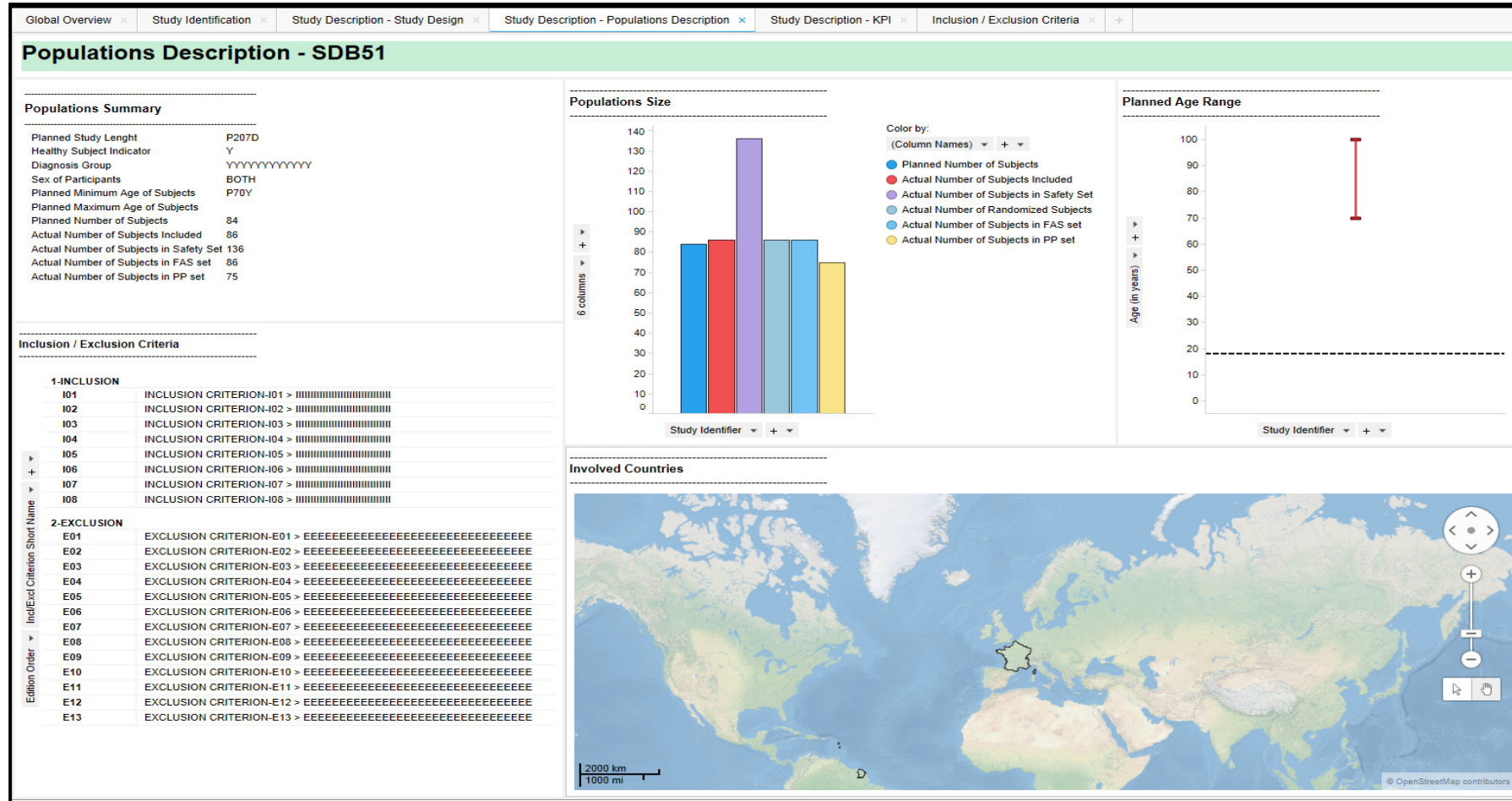
The screenshot displays the 'Study Identification' interface with the following components:

- Filters to restrict the studies' list:**
  - Brand:**  BRAND B (highlighted in red)
  - Project's Name:** (All) 1 values
  - Study's Name:** Multiple entries with checkboxes, including SDB51 (highlighted in green).
- Select your study in the following list:**
  - Study Identifier:** SDB51 (highlighted in green)
- Corresponding Study Summary:**

Brand	BRAND B
Project's name	RRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRR
Study name	RRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRRR
Study Code	SDB51
Study title	TITLE OF STUDY XXXXXXXXXXXXXXXXXXXXXXXXXX
Study Primary Objective	OBJECTIVE XXXXXXXXXXXXXXXXXXXXXXXXXX
Clinical Study Sponsor	ISS
Study Type	INTERVENTIONAL
Planned Country(ies) of Investigational Sites	France
Study Indication Type	TREATMENT
Study Indication	INDICATION X



# VISUALIZATION – SOME EXAMPLES...



# CONCLUSION & ACKNOWLEDGMENTS

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