IMPLÉMENTATION ET GESTION DE MÉTADONNÉES D'ÉTUDES

DANONE NUTRICIA RESEARCH

CONTEXT

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

↪ Objective – Create a Clinical Metadata Catalogue

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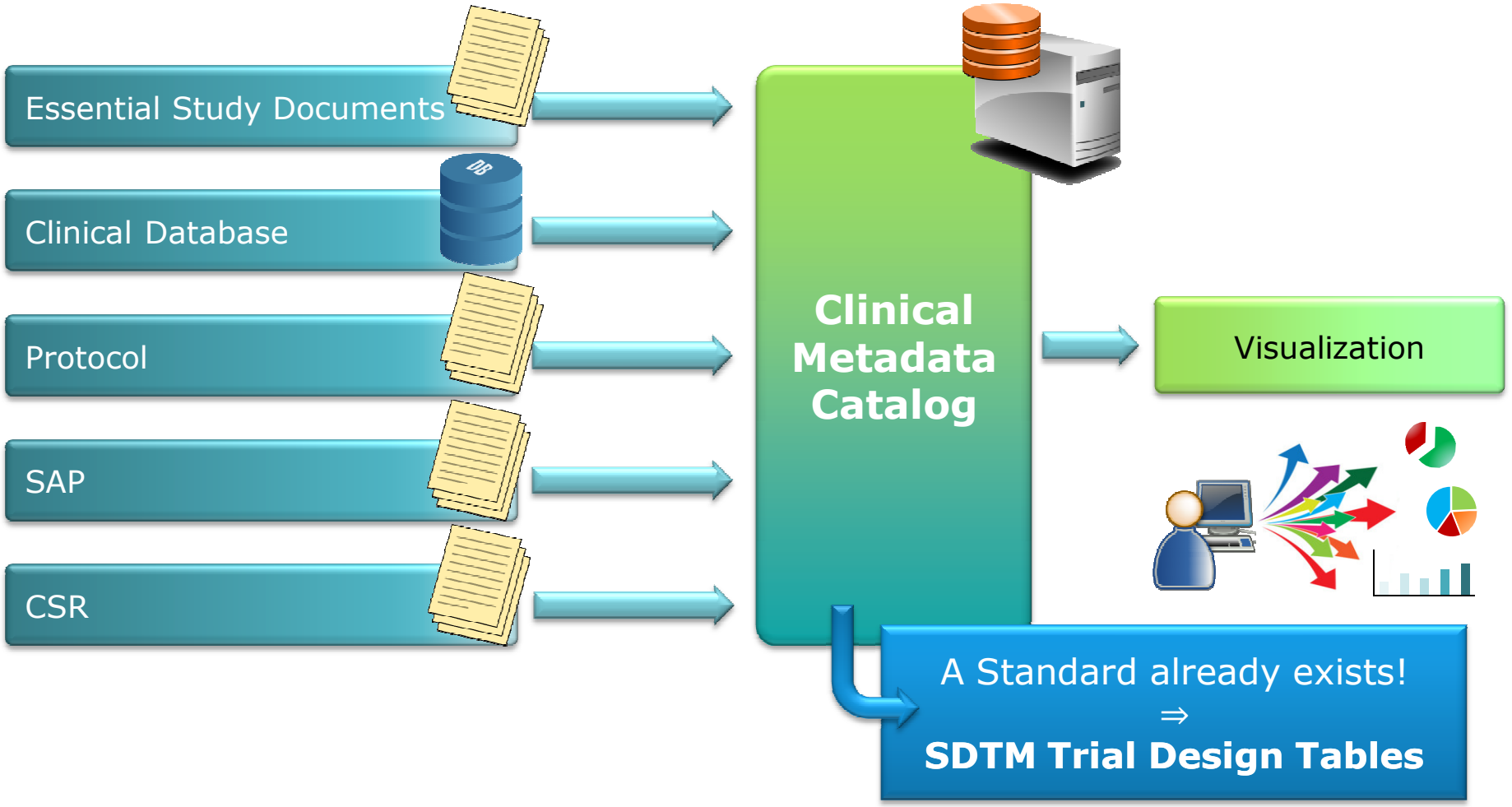
CLINICAL METADATA CATALOG



TRIAL DESIGN TABLES, WHAT IS IT?

- 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

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TRIAL DESIGN TABLES, WHY?

- 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

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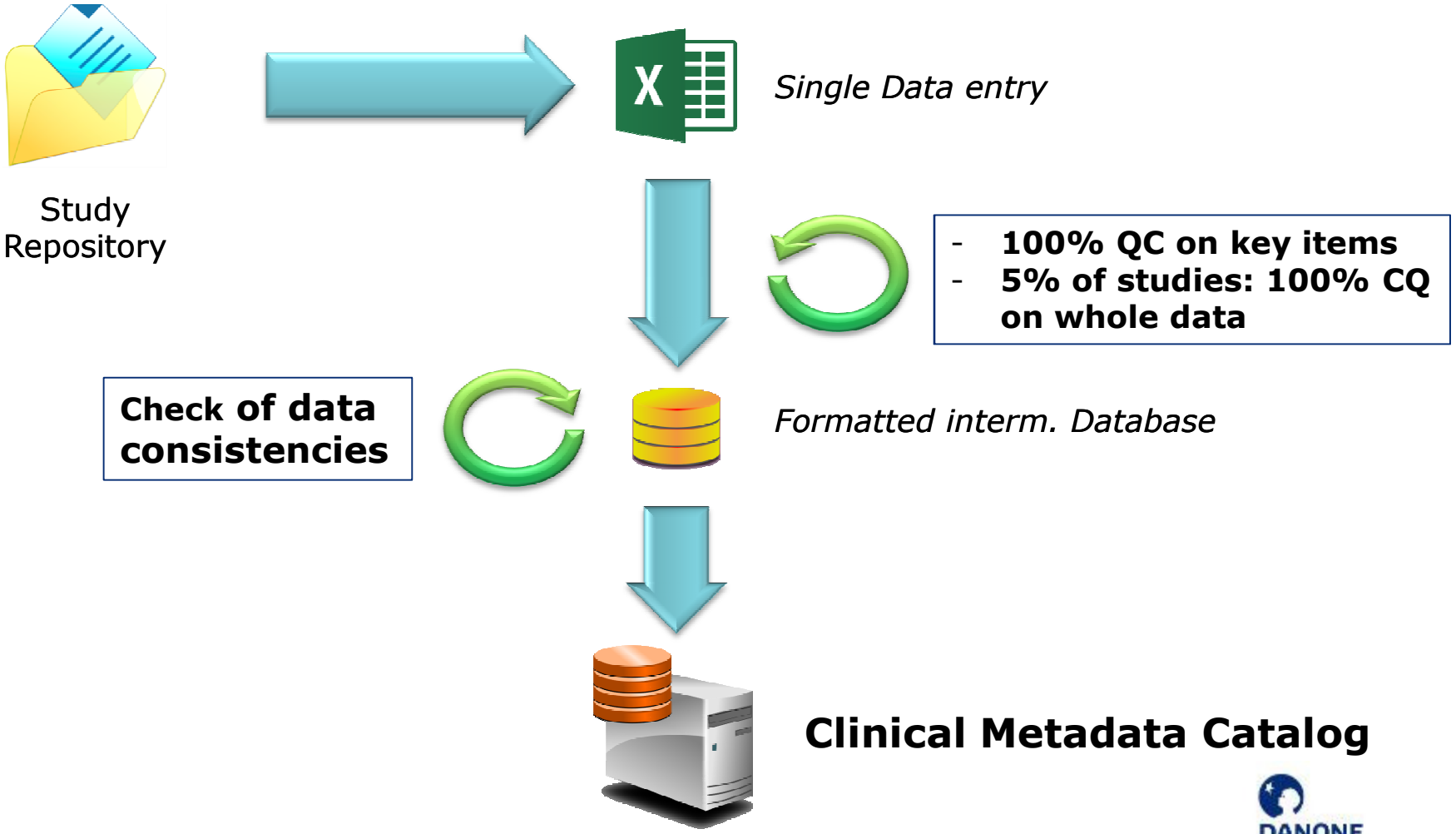
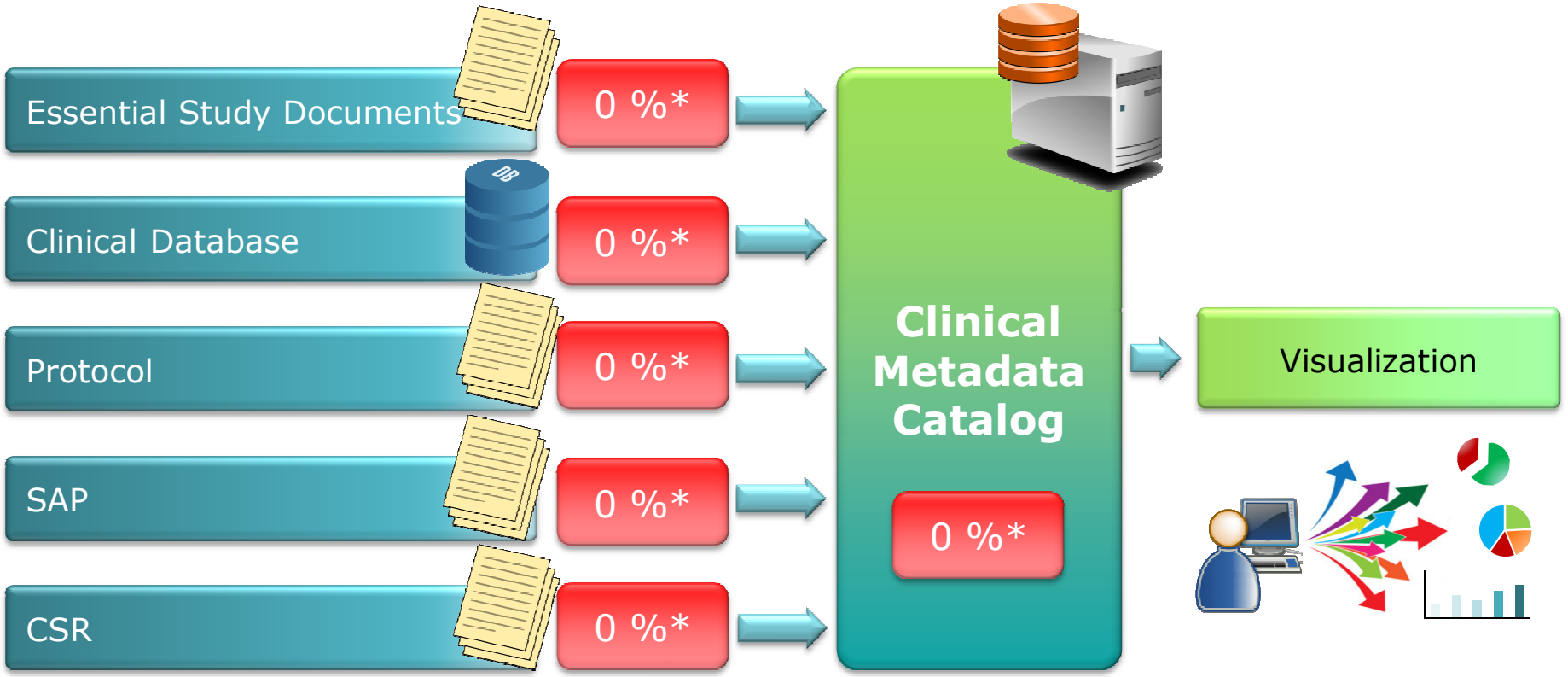
OLD STUDIES – PROCESS



OLD STUDIES – AUTOMATION



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

CURRENT STUDIES – PROCESS

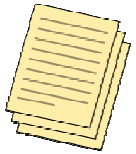
Study Milestones:

- **Protocol V1**
- **Protocol Amendments**
- **DB Lock**
- **Final Statistical Results**
- **Final CSR**

Clinical Database

+

Documents



Clinical Metadata Catalog

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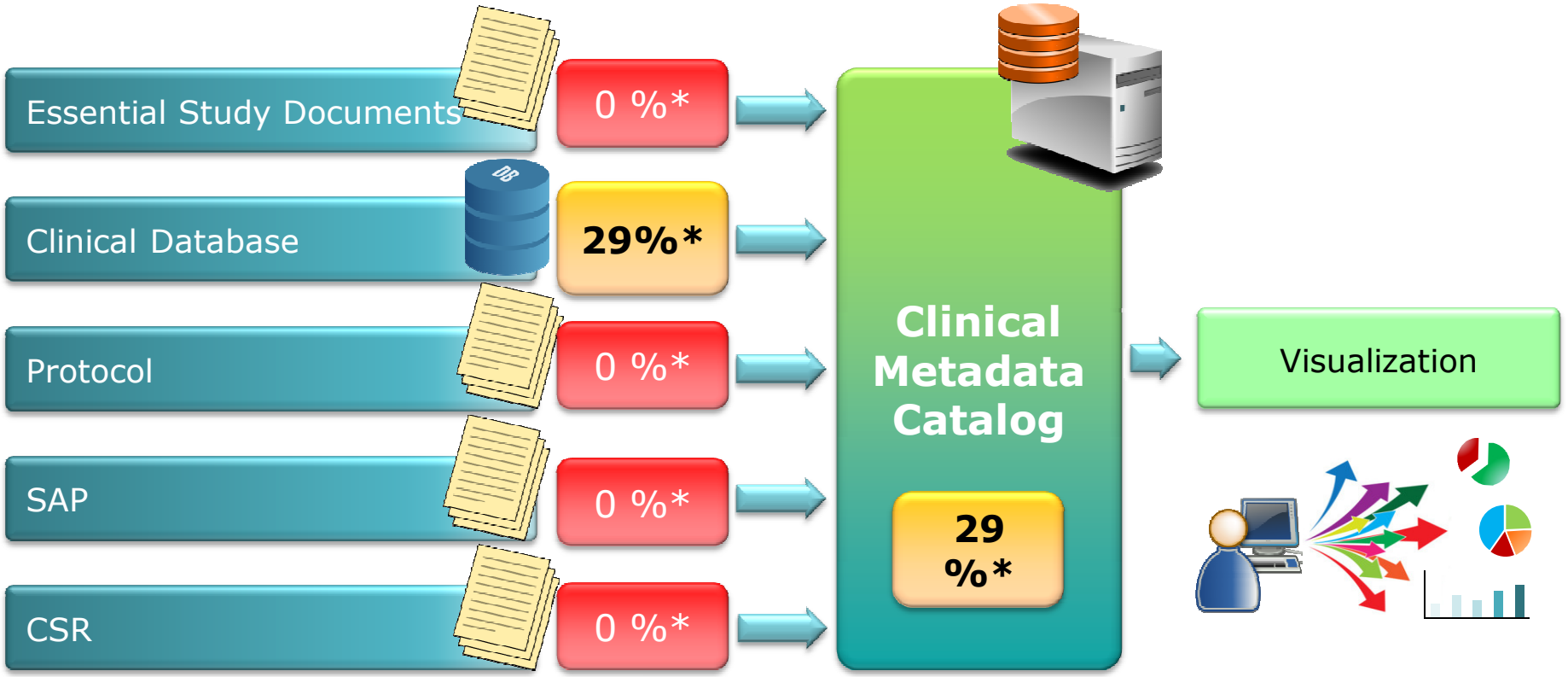
CURRENT STUDIES – AUTOMATION



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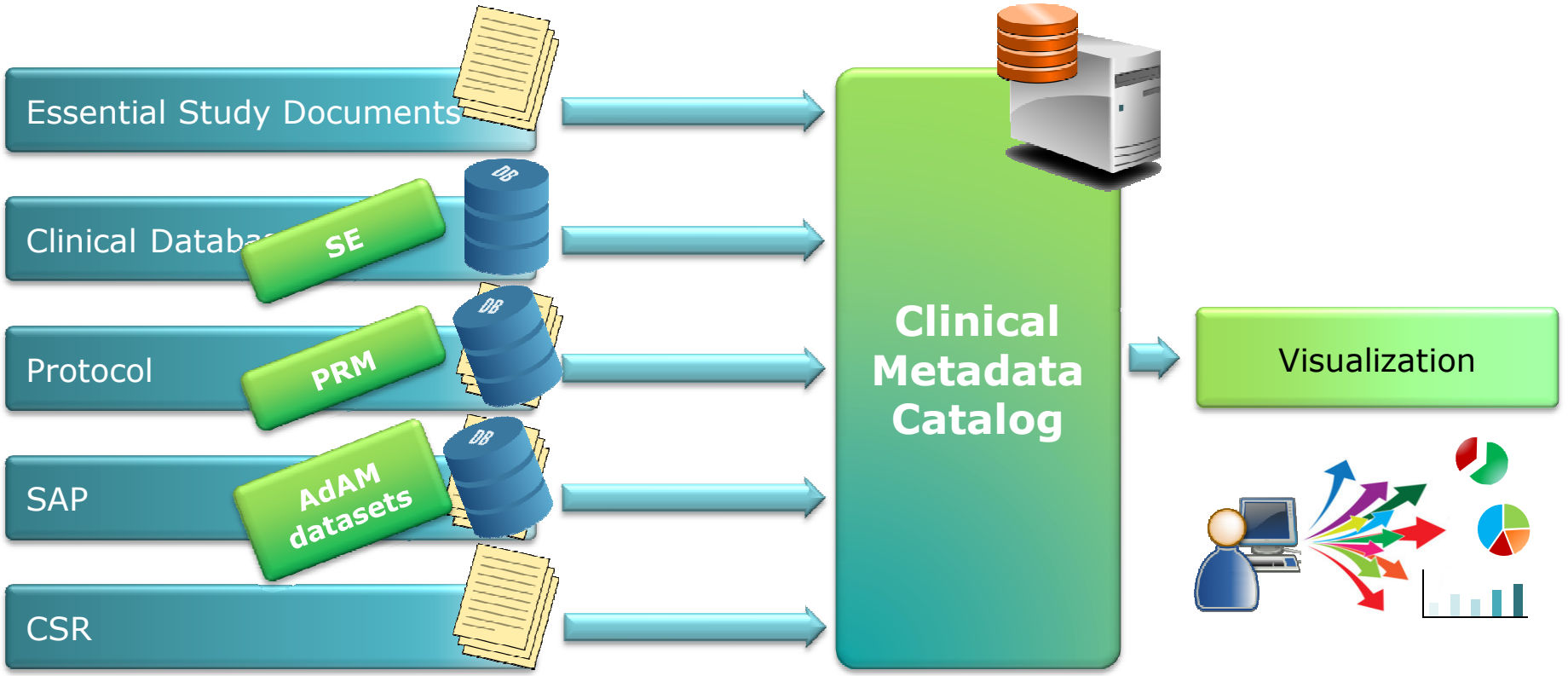
AUTOMATION – FUTURE PERSPECTIVES



Objective: Percent. automation of Clinical Metadata Catalog **≈ 90 %**

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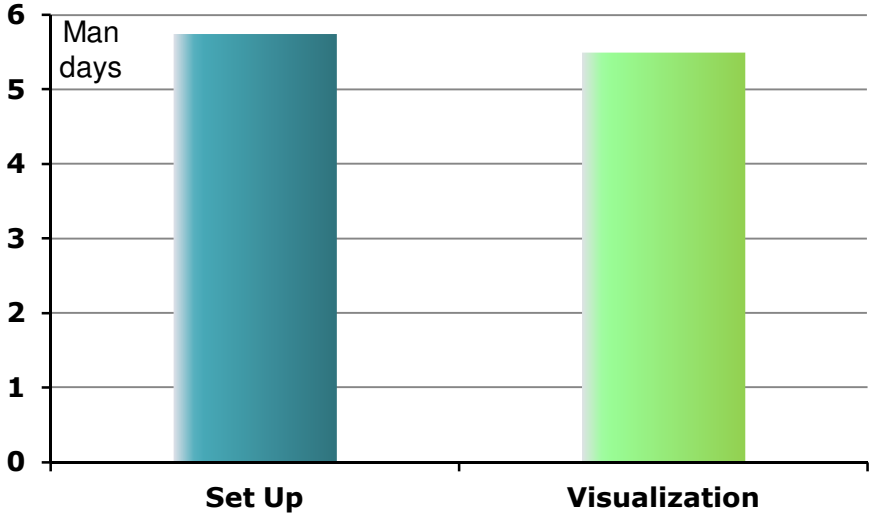
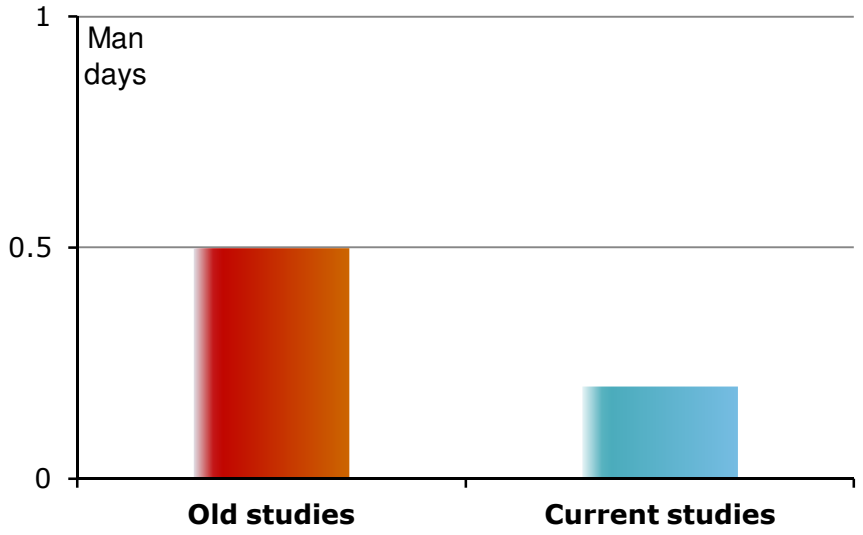
IMPLEMENTATION RESOURCES



Process

Implementation



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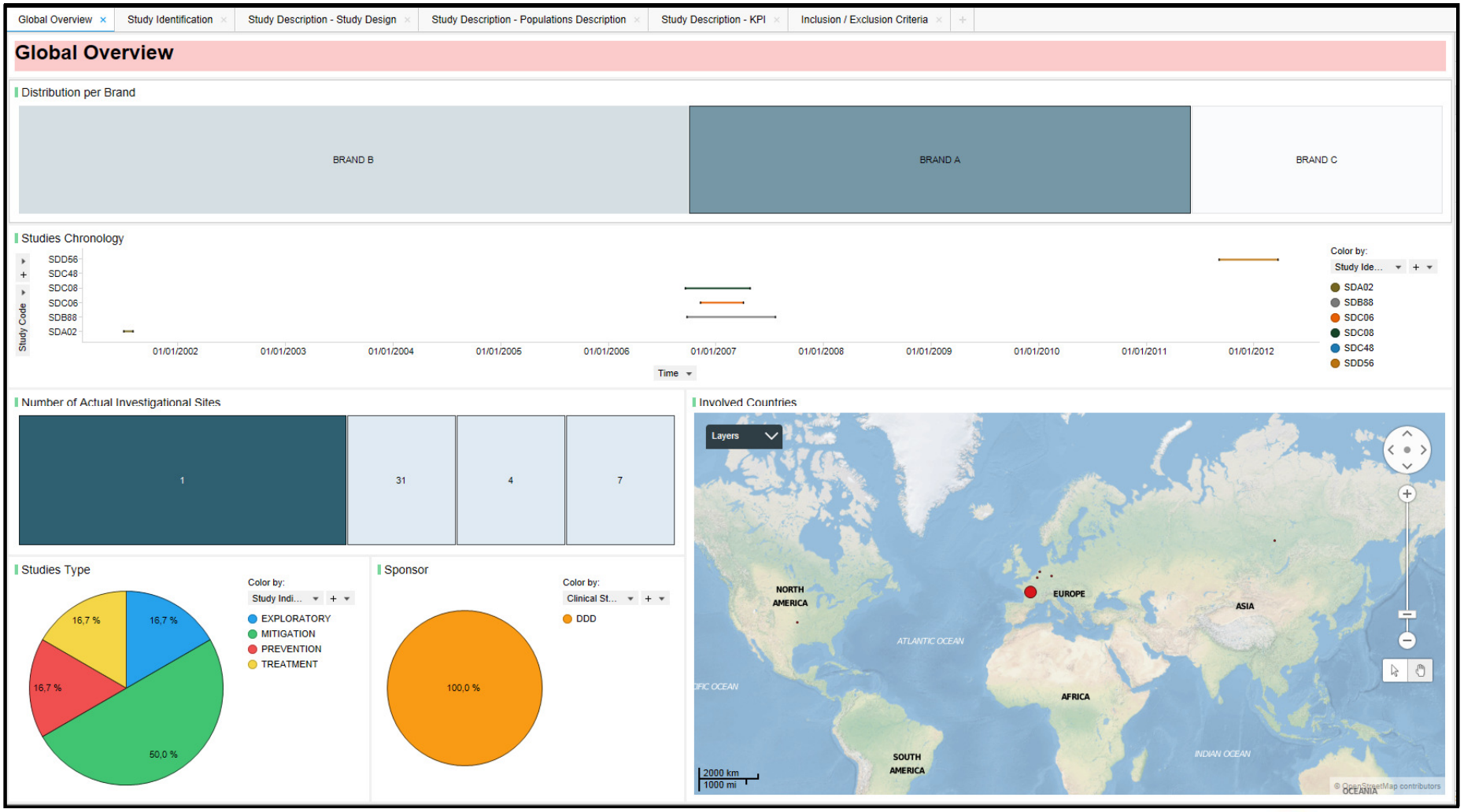
VISUALIZATION – SOME EXAMPLES…



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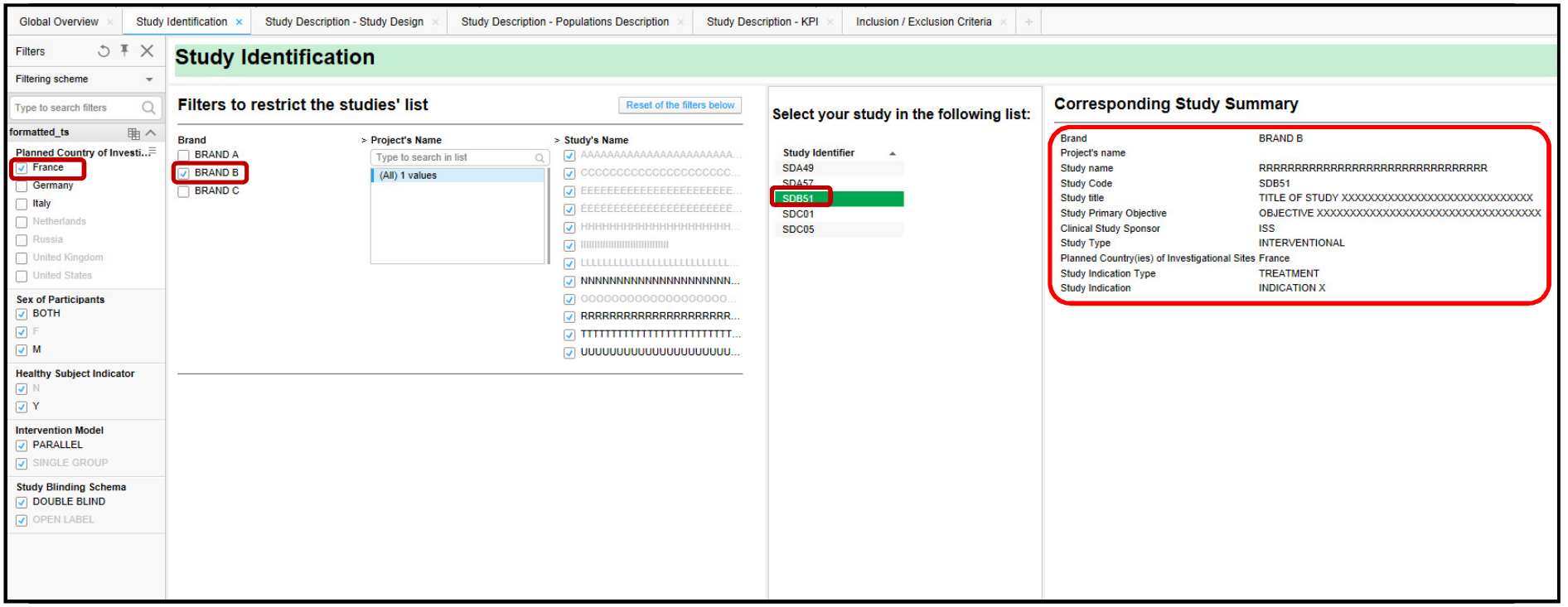

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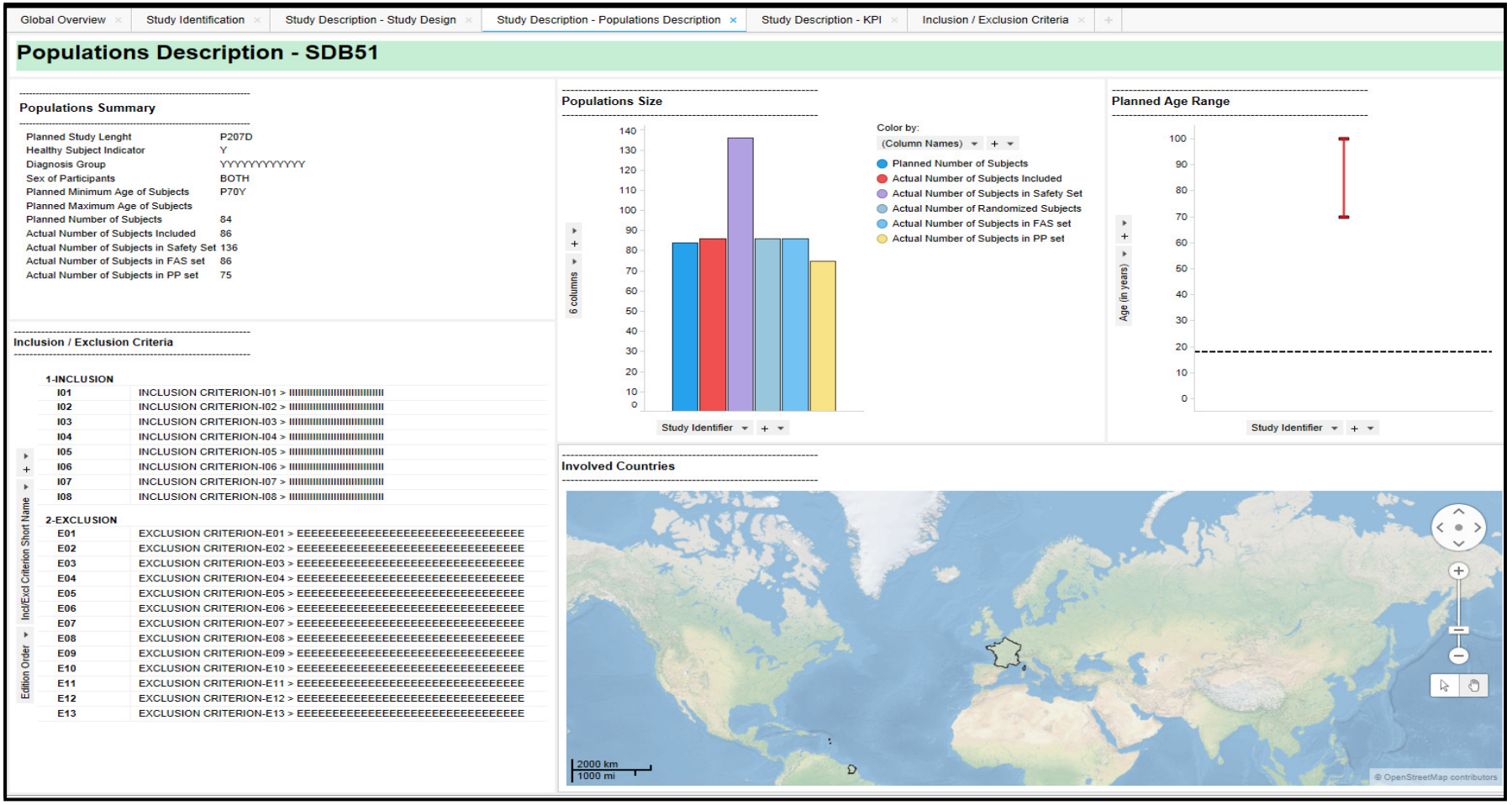

CONCLUSION & ACKNOWLEDGMENTS