

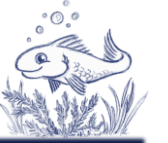
Katja Glass
Consulting

OpenStudyBuilder

The Game Changer!

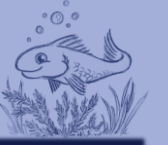


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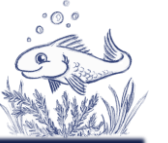
Agenda



- Introduction
 - OpenStudyBuilder
 - Game Changer
 - Summary
-



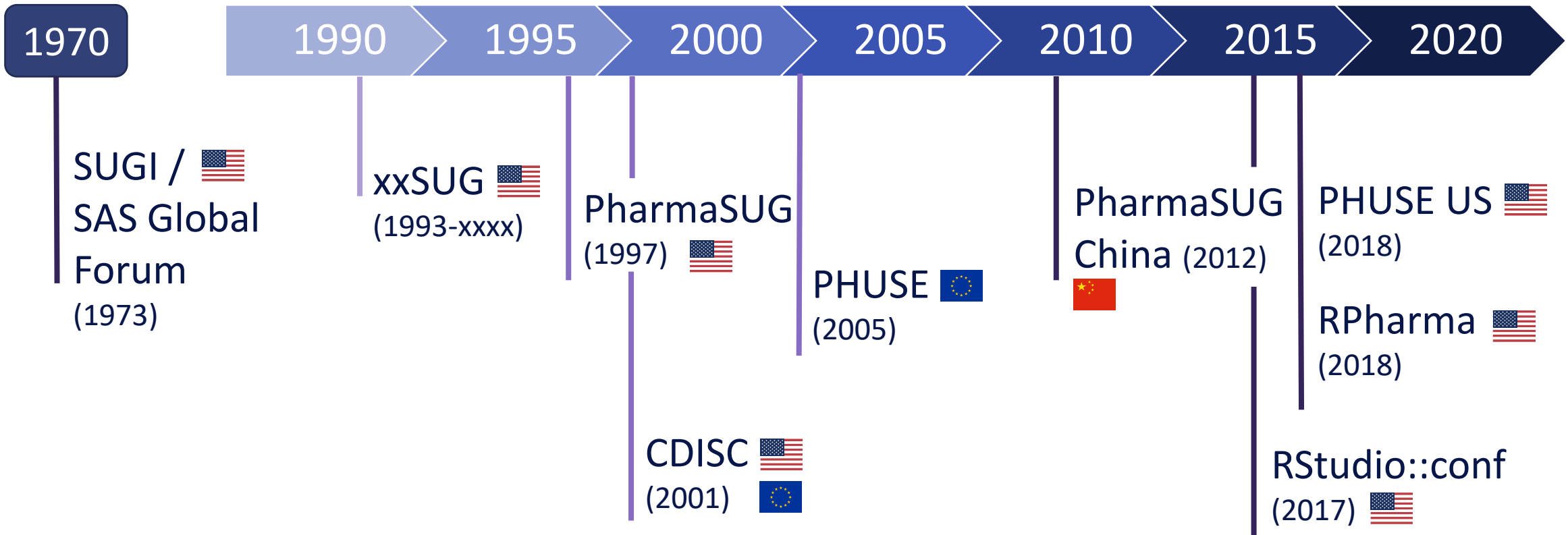
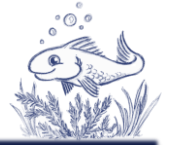
Introduction



- Community has grown over years
- Community conferences
- Working groups



Introduction - Conferences



Introduction

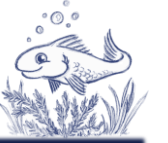


- Community conferences
 - Exchange experiences
 - Discuss challenges & solutions
 - Tips & tricks
 - Business focused

- Working groups
 - Closer collaborations
 - Common guidelines
(Good Programming Practice, TLF white papers, ADRG Guide, ...)
 - Dive deep into topics
(PHUSE repository, LinkedData, Emerging trends, Education, ...)



Introduction



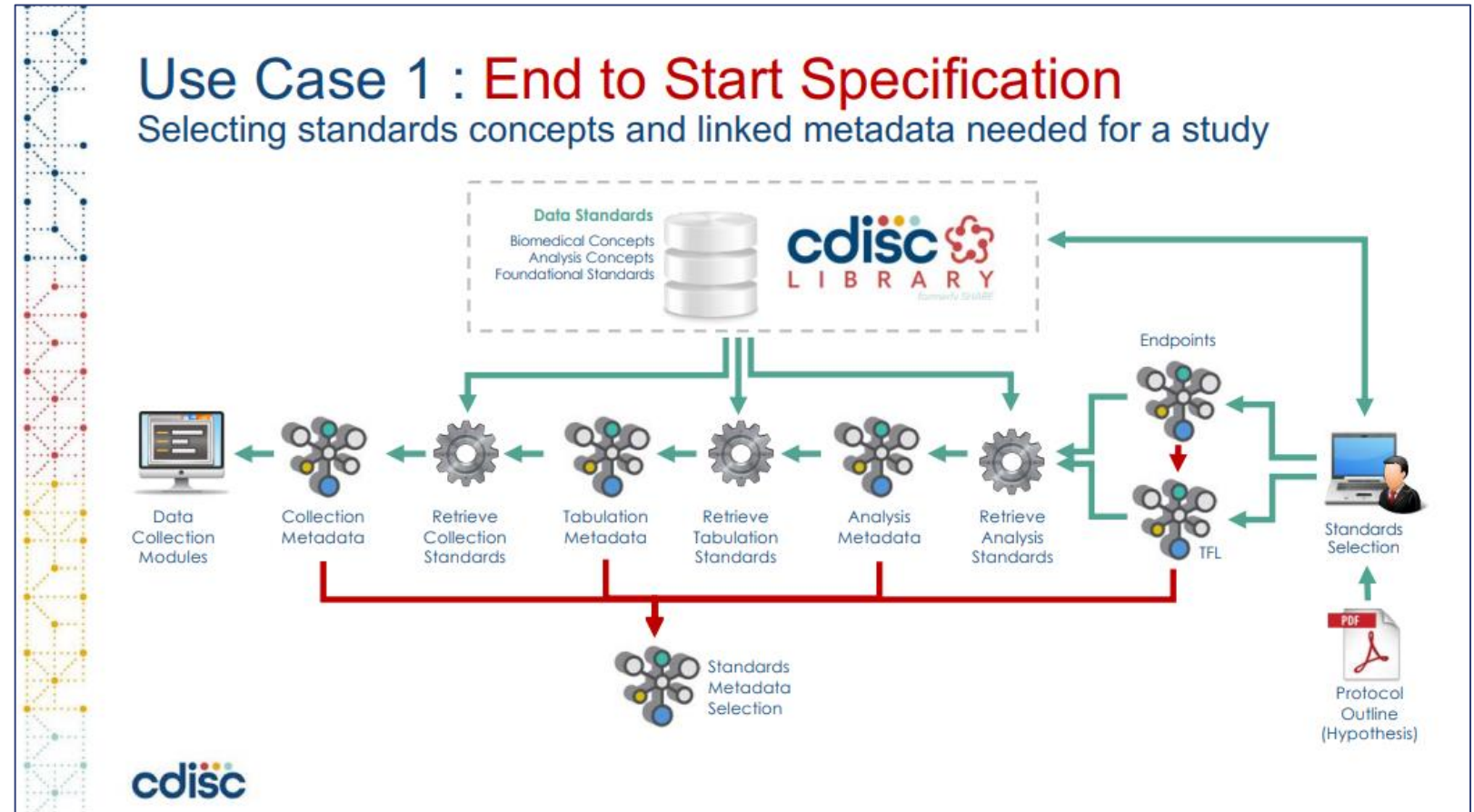
- What's next?
 - **Open Source**
- Ultimate collaboration
 - Share tools
 - Share environment
 - Build common understanding



Introduction



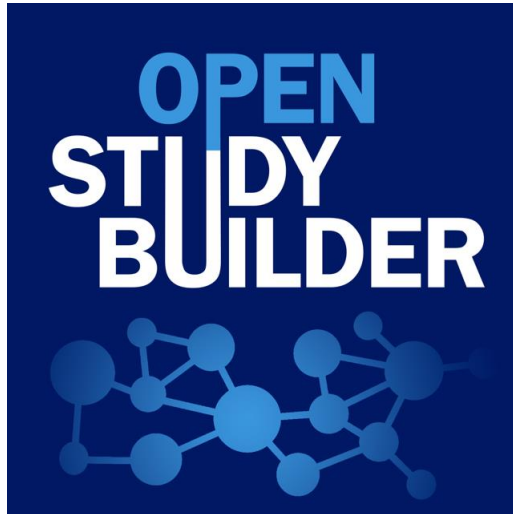
➤ Start-to-End Vision CDISC 360°



Introduction



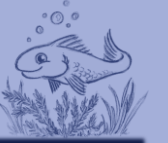
- Vision is not enough -> Solutions required (Open Source)



Digital Data Flow



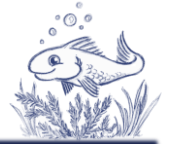
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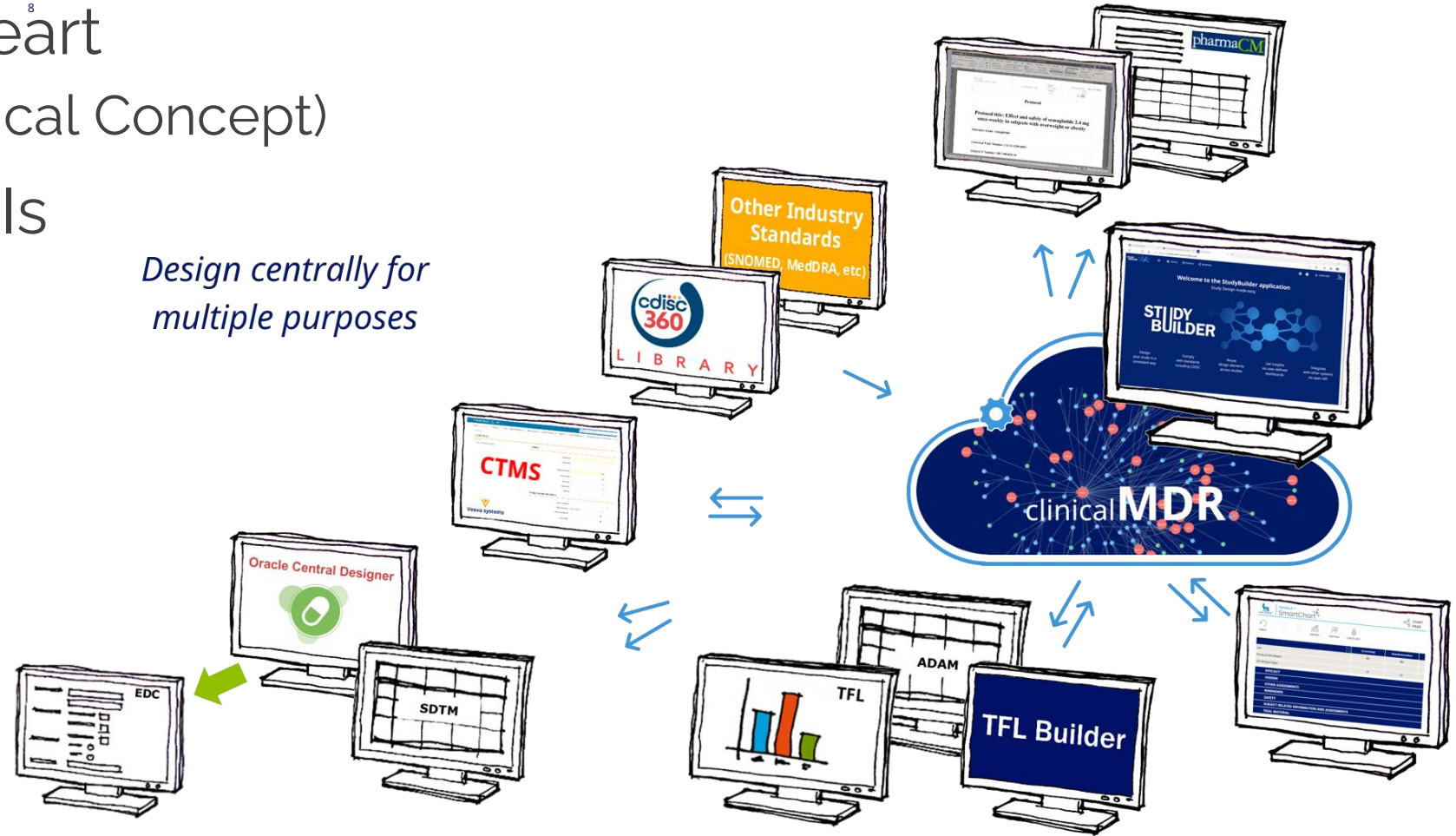


OpenStudyBuilder

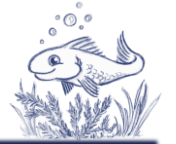


- MDR - the heart⁸
 - BC (Biomedical Concept)
- Standard APIs

Design centrally for multiple purposes

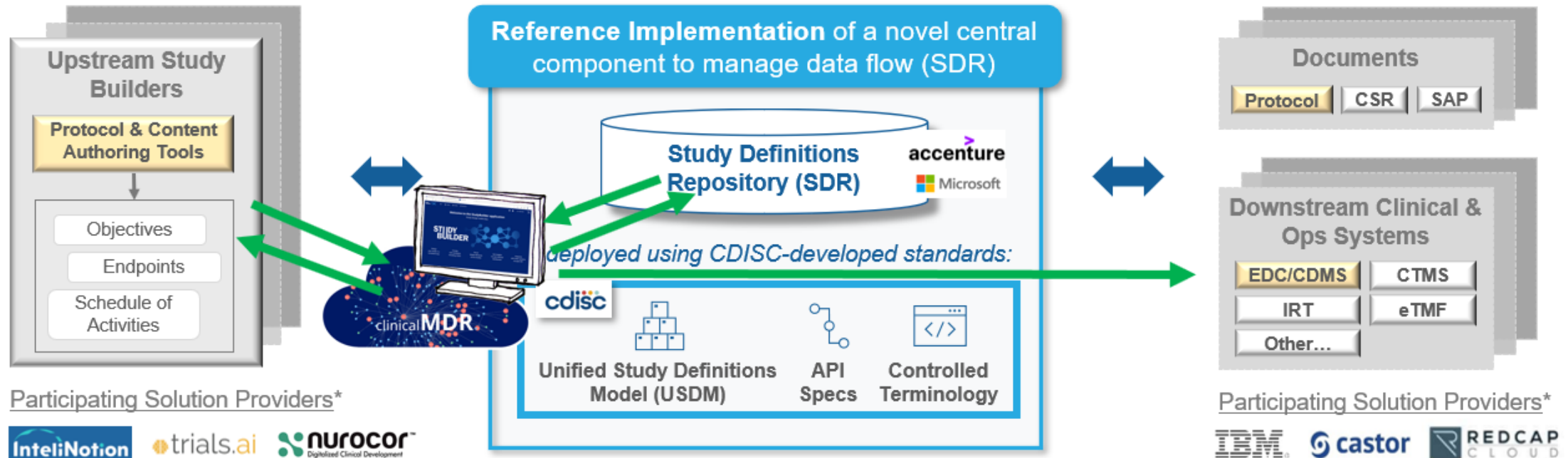


OpenStudyBuilder

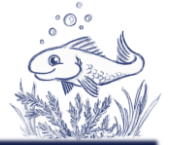


- Standard APIs (DDF compliance)

Digital Data Flow



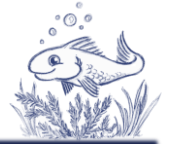
OpenStudyBuilder



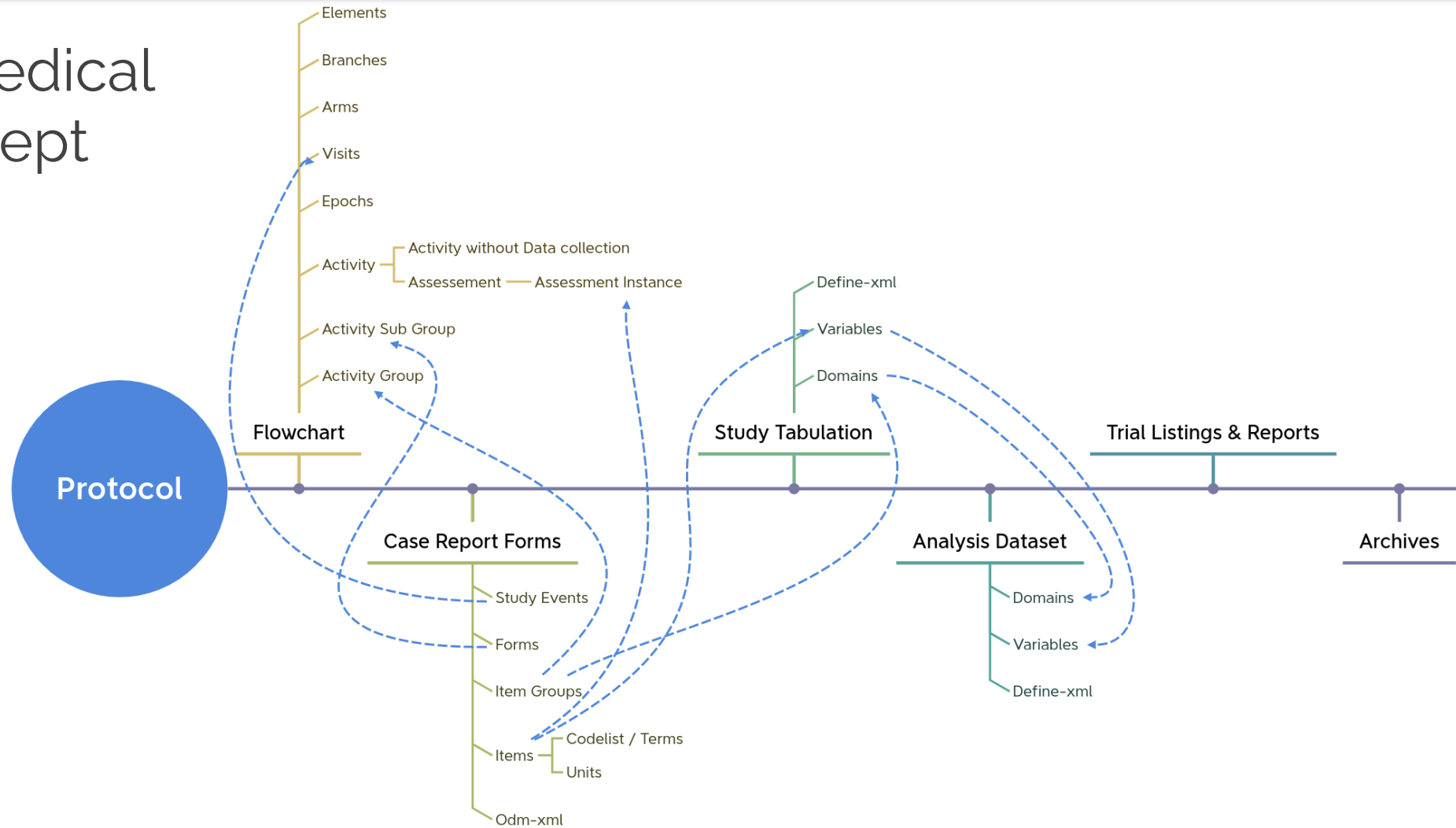
- Tool compliant with DDF
also compliant with OpenStudyBuilder



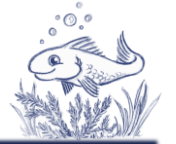
OpenStudyBuilder



➤ Biomedical Concept



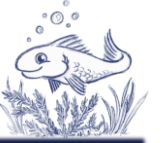
OpenStudyBuilder



- Why OpenStudyBuilder now? DDF going forward
 - Need a solution now
 - Migrate legacy MDR system
 - Practical quick decisions
 - Currently discrepancies for API, adapter is on the way
 - BC internally not exactly what CDISC will use as base (likely)
 - Modern approaches: concept based standards (linked data)
 - Sustainable model for maintenance and integrations



OpenStudyBuilder



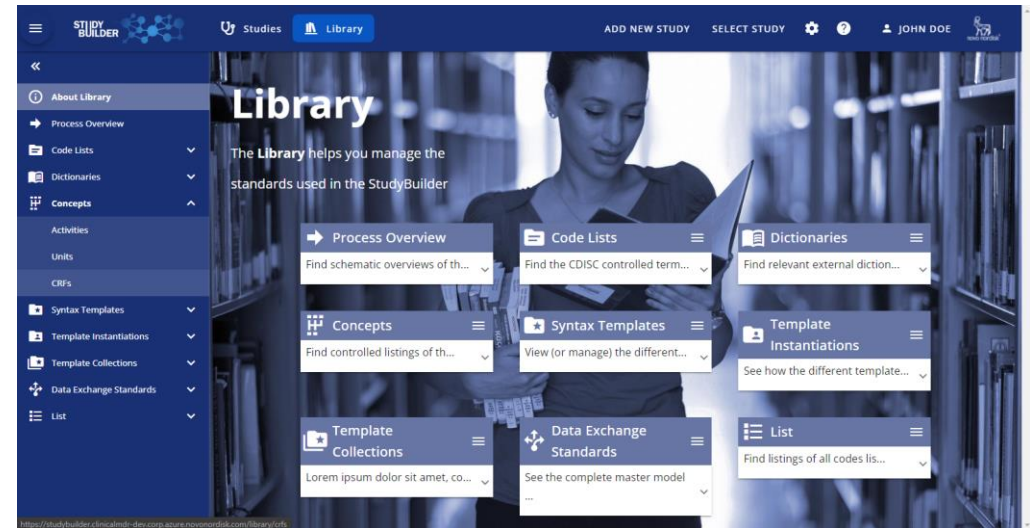
- Why Open Source?
 - No new “custom tool”
 - Industry standards (CDISC, DDF)
 - Active player in industry transformation
 - Open Source Opportunities
 - Benefit from collaborations
 - Benefit from future tools and extensions



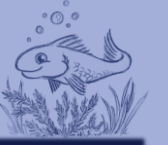
OpenStudyBuilder



- Status
 - MDR with CDISC and sponsor standard
 - Protocol information
 - Trial Summary information
 - First SDTM definitions
- Running evaluation environment
 - Workshop & participant play around
 - CDISC & DDF share next steps
 - Q3/Q4 with rollout available for anyone



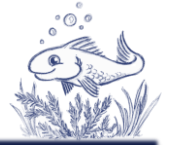
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Game Changer



- Impact of MDR?!

Codelists

Trial
Domains

Upgrading

Mappings

- Maintenance?!

- Integration?!
-

Game Changer



- Open Source allows flexibility & easy integrations
 - %downloadCodelists
 - Review & edit metadata/codelists
 - Graphical tool
 - Excel export / import (please don't)
 - Multiple solutions, standard interfaces!
 - Use case: Word addon for Protocol creation
 - Use case: Maintain Trial Domains
 - Use case: Information Gain
 - Use case: Mapping
 - Use case: EDC connection



Game Changer



- Open Source focus
 - Generic company unspecific
 - Showcases, examples, hands on
 - Customization, adoption as needed
 - Discuss solutions
 - Vendors and Pharma working hand-in-hand
 - Implement once, reuse everywhere



Game Changer



- What do we need for the change?
 - Willingness, business open-source support
 - Ideas, implementation and publication
 - Pilots & Pioneers
 - Community

- High interest -> Active Join



Game Changer

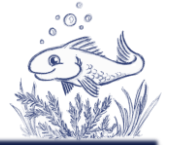


- What bigger initiatives do we have
 - DDF (very technical)
 - CDISC & COSA (standard driven)
 - OpenStudyBuilder (business driven)
 - Pharmaverse (R driven)
- Impact to our way of working

Digital Data Flow

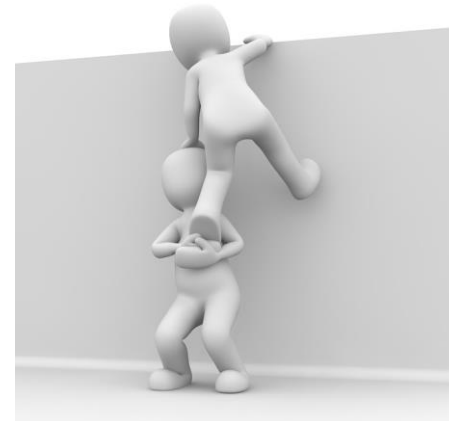


Game Changer



- Learn how to work in open-source environment
 - Feedback
 - Provide also small tools / ideas publicly (license)
 - Provide updates

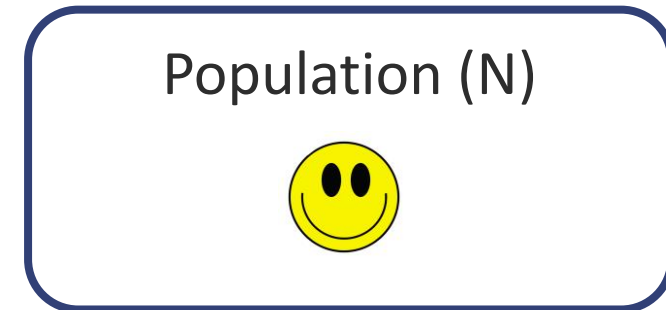
- Enable
 - Higher skillset
 - Different perspectives
 - Network for discussions



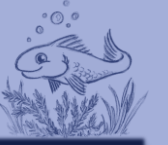
Game Changer



- Feedback wall
 - How do you want to stay informed about open source projects?
 - Smiley for your preferences (+ population N)



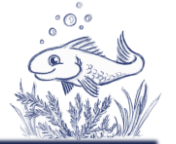
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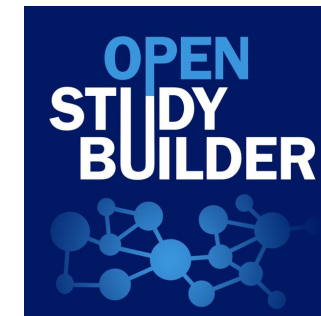
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Summary



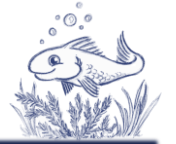
- Open Source as next level collaboration
- OpenStudyBuilder as technology and business driven open source solution
 - Rollout internally in Q3 2022
 - Open Source rollout planned for Q3/Q4
 - Tool in production
 - Focus Standard maintenance, CRF, Protocol
 - Hope for collaborations
- Mindset change



 join, create or support open source



Summary



➤ Information

➤ OpenStudyBuilder Homepage

<https://novo-nordisk.gitlab.io/nn-public/openstudybuilder/project-description/>

➤ CDISC Open Source Alliance (COSA)

<https://cosa.cdisc.org/>

➤ DDF Initiative

<https://www.transceleratebiopharmainc.com/initiatives/digital-data-flow/>

➤ Pharmaverse

<https://pharmaverse.org/>

➤ Open Source Portal

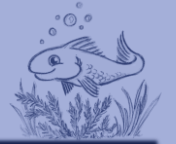
<https://www.glacon.eu/portal>

➤ Feedback / Questions to Katja

OPEN SOURCE PORTAL

For Clinical Study Evaluations

Questions?



Katja Glass Consulting

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www.glacon.eu

www.glacon.eu/portal
