



RETHINKING
CLINICAL
DEVELOPMENT

THROUGH
DIGITAL
INNOVATION

OpenStudyBuilder is the open-source solution for the industry, establishing a **single, standardized source of truth for digital study design specifications**, unlocking data- and AI-driven operational and scientific excellence across clinical development



#PoweredByOpenStudyBuilder



clinical **MDR & SDR**

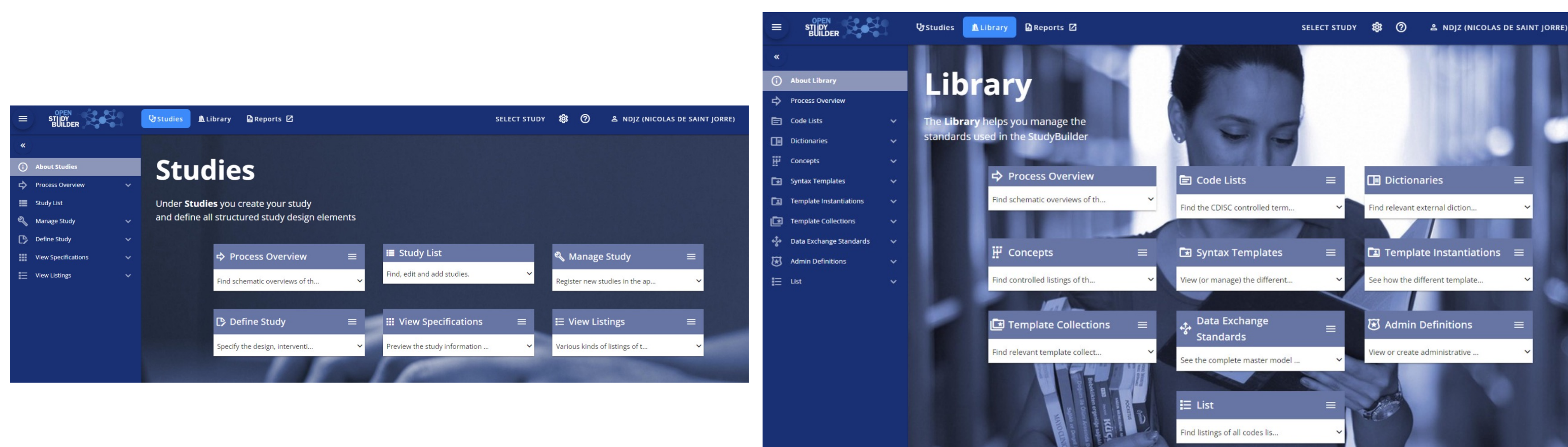
OpenStudyBuilder

open source enabling a digital data flow

- OpenStudyBuilder is shared as open source under COSA by Novo Nordisk
- Collaborate with TransCelerate as a Digital Data Flow (DDF) compatible solution
- Collaborate with CDISC, e.g. for Biomedical Concept Development & Enhancements



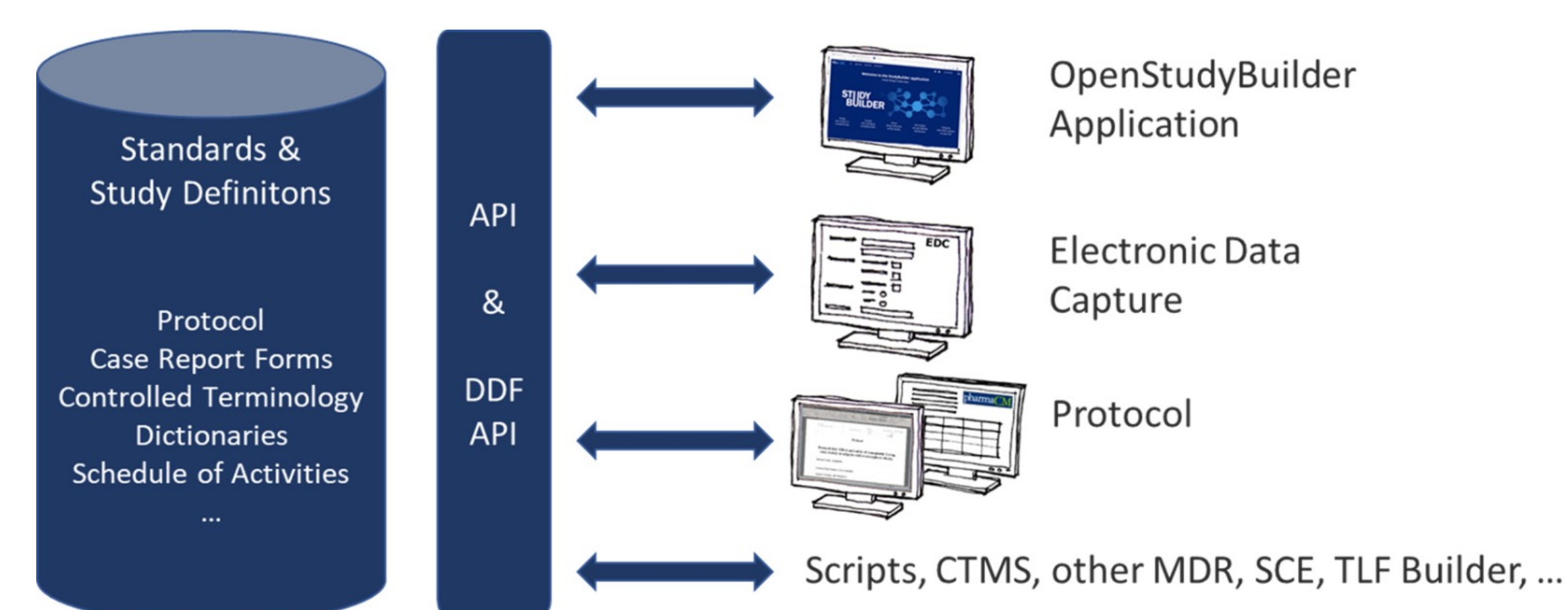
Study Specifications & Standards Management



- Single metadata source for key deliverables e.g., protocol, CRF, SDTM, ADaM, CTR, TFL
- Standardization through controlled terminology, dictionaries, templates
- Built-in compliance with external and internal standards
- More end-to-end consistency due to reusability and linkage
- Facilitation of more automation and content reuse through an open interface (API)
- Metadata-driven creation of structured protocol content

OpenStudyBuilder as a Multisource System

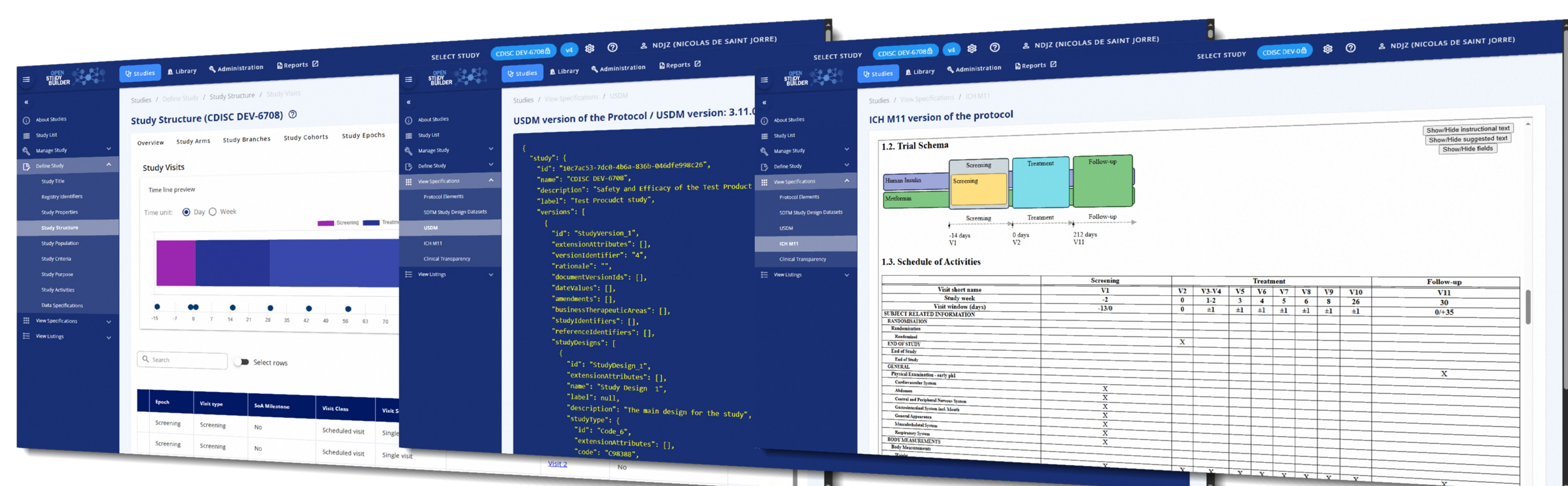
- Protocol harmonization through Standards
- Full connectivity to any kind of systems through APIs – Including USDM compatibility
- Maintenance of standards, like eCRF standardization and utilization in downstream EDC systems



- Value driven roadmap and development
- Continued improvements for protocol setup
- USDM and ICH M11 support

- Enabling metadata management
- Operationalization of Biomedical Concepts
- Linking with CRF to drive EDC automation

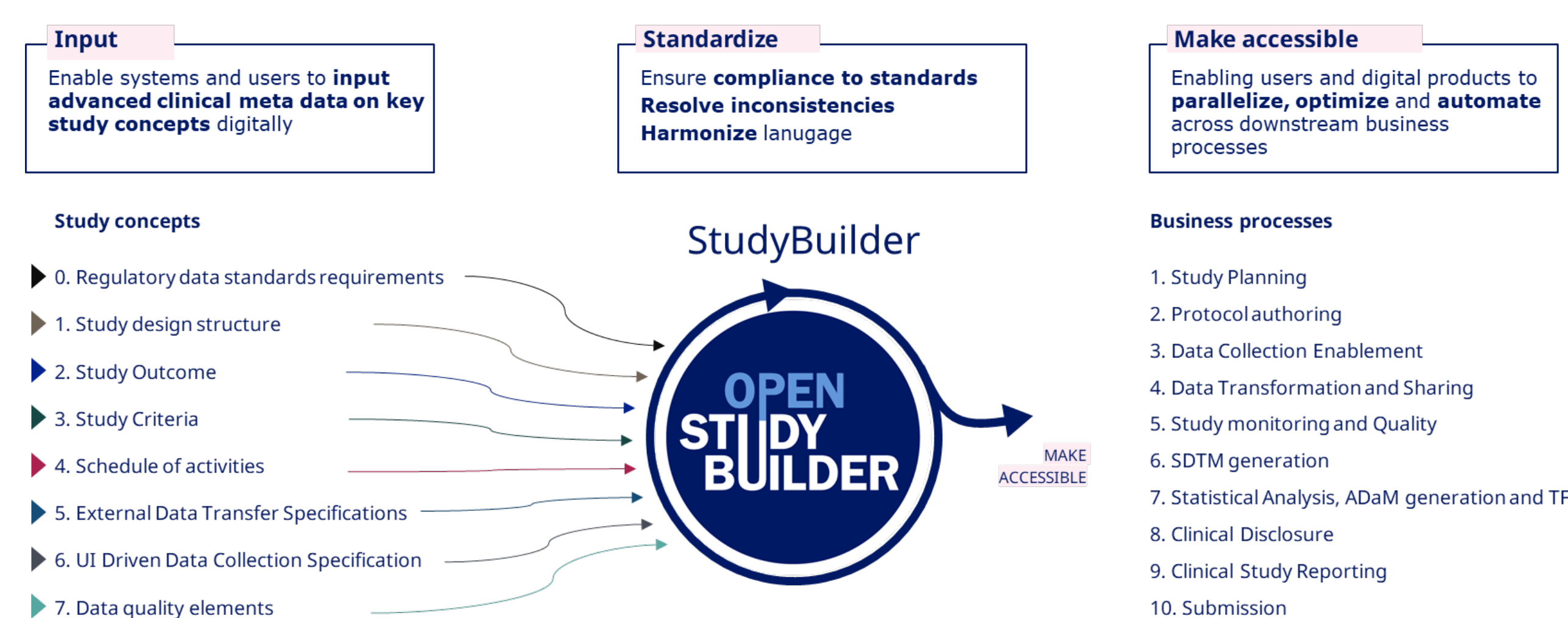
From the Digital Protocol Metadata to the ICH M11 via USDM



Define Structures like Timeline, SoA, etc. in UI

Transfer into USDM version 3.11

Visualize the USDM as M11



Optimized business processes