Digital Data Flow and **OpenStudyBuilder** USDM & M11
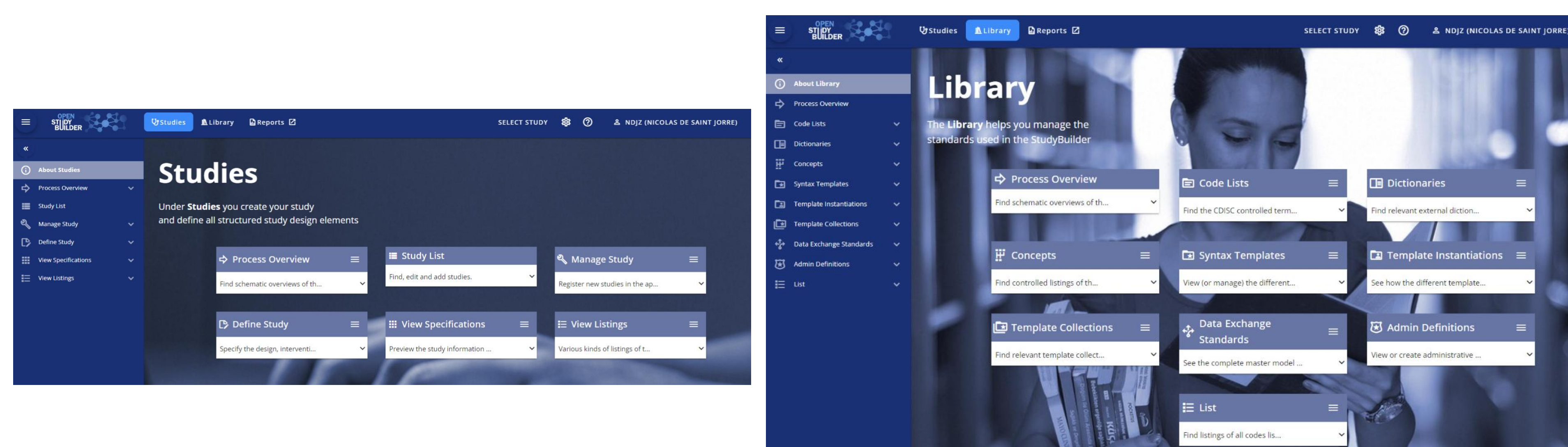
clinical MDR

A dedicated module enables **OpenStudyBuilder** to convert our metadata into the Unified Study Definition Model (USDM) and exposes the result through a compliant API endpoint

- 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
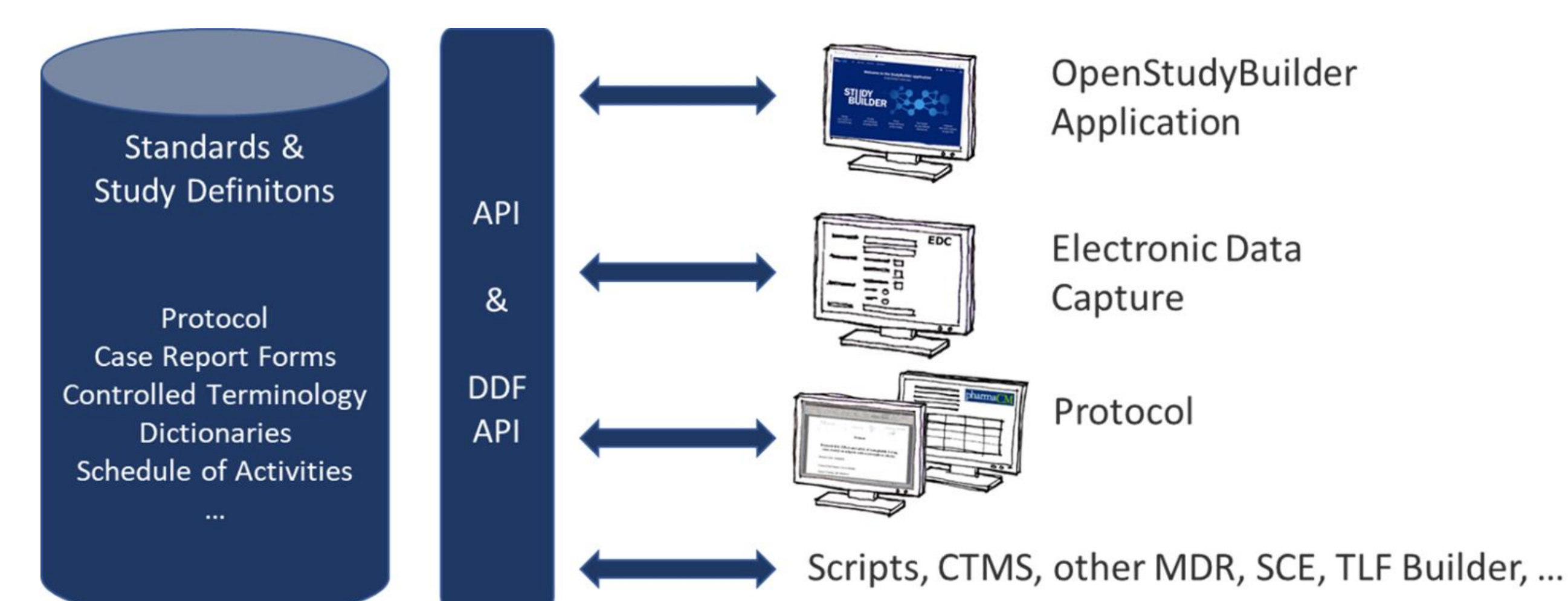
Study Specifications & Standards Management

- 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
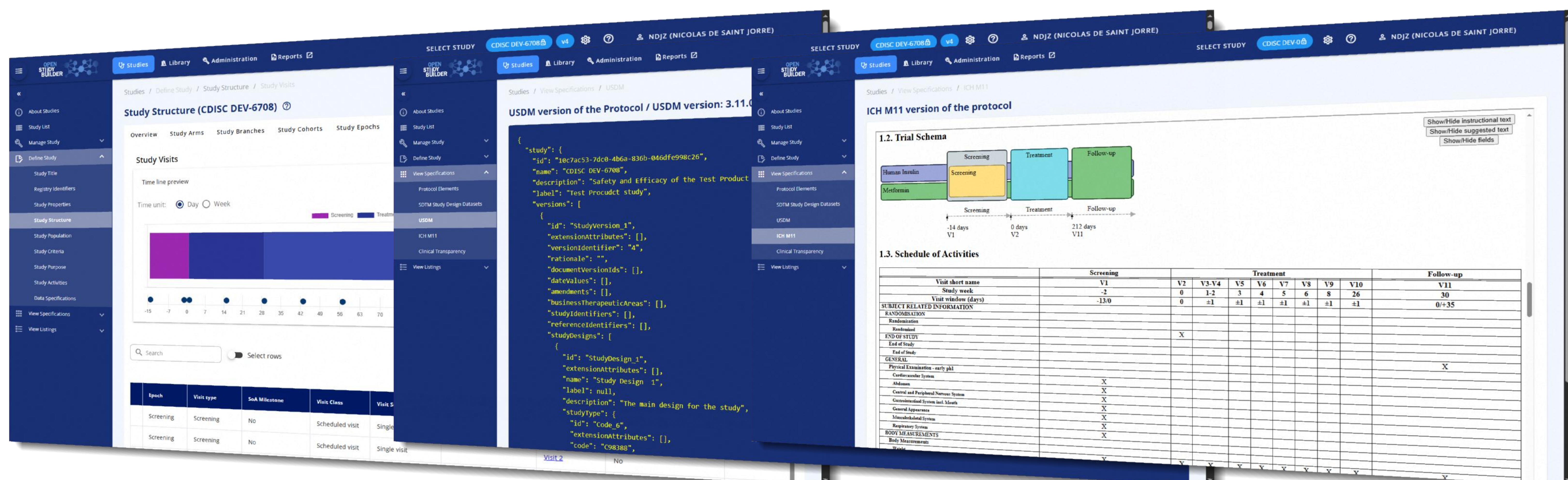
OpenStudyBuilder as a Multisource System

- 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

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**