

OpenStudyBuilder SWOT (based on PoC)

Strengths

Project

- Experience and competence level
- Strategic partnership with XClinical to develop system into commercial product (co-developed with shared risk)

System

- Increased efficiency as a consequence of structured re-use
- Shared environment leading to improved metadata quality
- Technology choice

Opportunities

Project

- Influence future industry standards via CDISC360 and TransCelerate DDF

System

- Improved business insight through linking related elements via modern graph database allowing for intelligent dashboards and search functionality
- FAIR based data sharing through transparent API-based architecture

Weaknesses

Project

- Perception of current state not reflecting actual status
- Peers can manage with less?

System

- Higher expectations than what is realistic to deliver due to business process complexity

Threats

Project

- Too few SME resources and high dependency on few resources
- Cloud competences and support a bottleneck
- Insufficient cross organisational allocation/commitment
- Dependency with other projects (MUSTANG and CTMS)

System

- Lack of integration capabilities in consumer systems preventing realisation of business benefits
- System ends a NN custom solution and not as a commercial system

Commercialization Opportunities

Consulting

Setup, configuration, validation,....

Add-on Tools

Custom extensions, additional functionality,...

EDC Integration

Rave, Oracle, Veeva, Marvin, Castor, ...
Connectors

Hosting & Deployment

Custom hosting, managed service,...

Statistical Analysis

Tabulation tools,....

Commercialization Opportunities

Connect

- EDC as the combined focal point:
- Using study build as the connecting point between businesses to initially speed up study build time
- Avoid vendor lock – customer in control, customer empowerment
- Conceptualise and build more efficient protocol to build translation

Standardise to innovate

- Standardise study build across vendors and platform to provide centralised repositories of prevalidated data sets that can be used to enhance study build
- Highlight where non standard data is used to warn users where they are deviating (reduce the numbers/time of handoffs between business units)

Customer benefits

Faster study builds, automation

Faster to market

Shifting from Manual to Automated tasks allows for focus on value add

Business Benefits:

Increased Trust

Benefit from cross-industry

Level playing field for study collaboration

Focus on value add opportunities, microcosmos of products and managed services (services, technical, hosting, consulting)

Platform Benefits

Centralised, trusted place for data & study build

Resource sharing improves quality