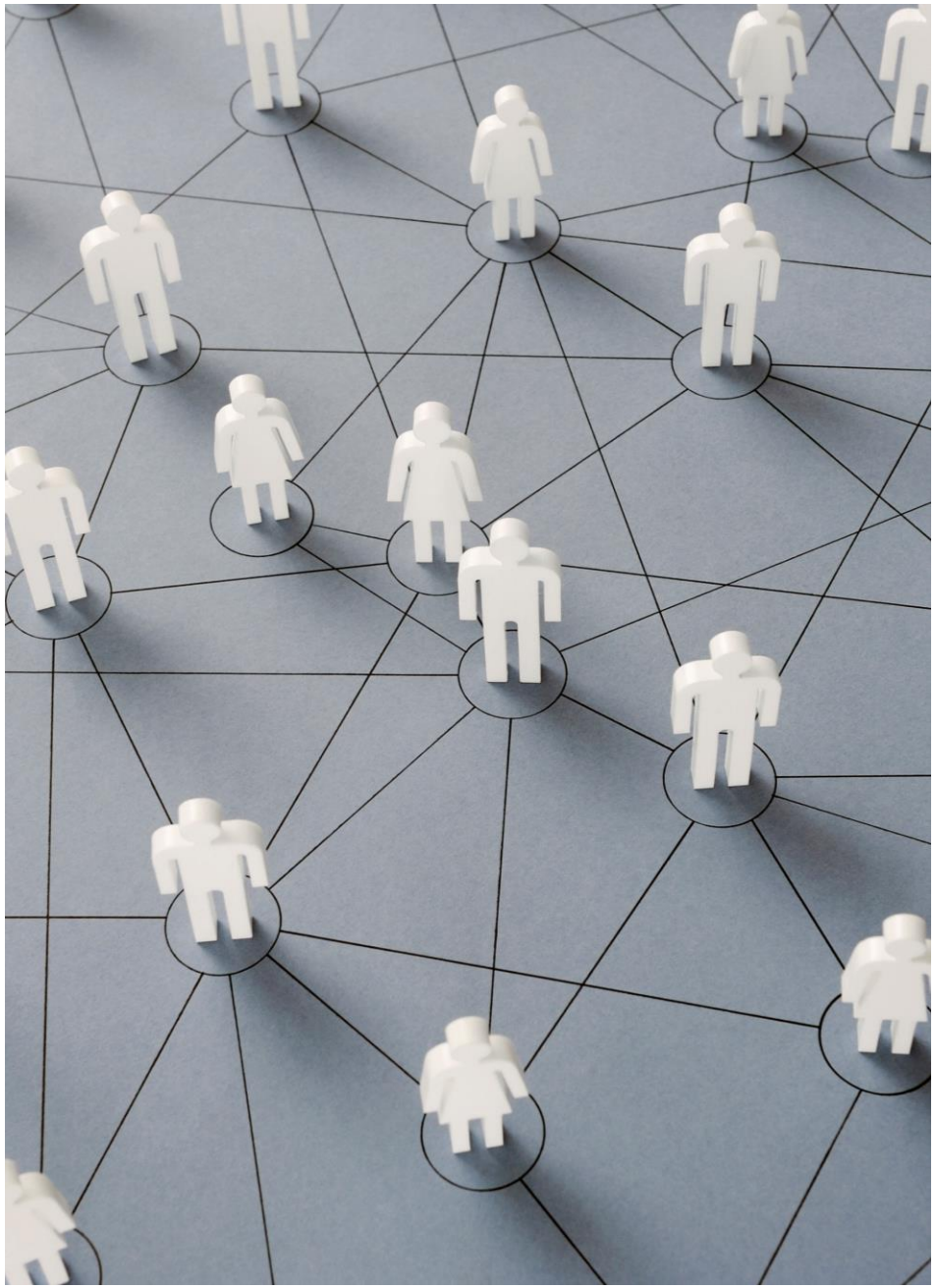


StudyBuilder Word ribbon

KOS/MCDY

29-April-2022

Agenda

1. Basic design principle
2. Demo
3. REST API
4. Discussion (SWOT, questions)

5. Lunch-break

Basic design principle

StudyBuilder ribbon

(Word add-in)

One-way connection!

Protocol

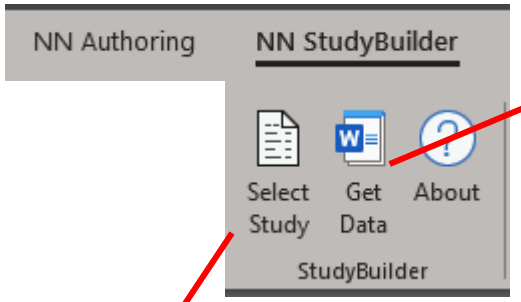
Only a Novo Nordisk specific version is available for now

StudyBuilder ribbon

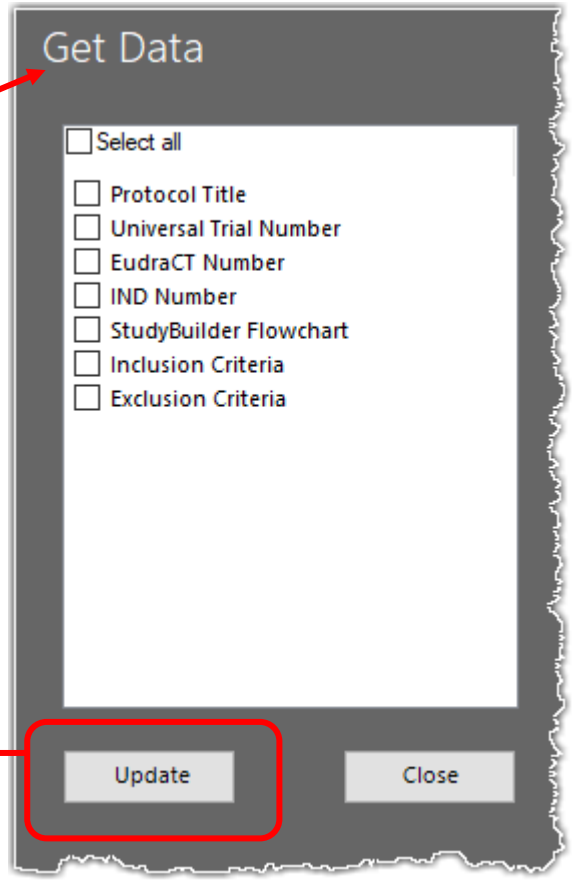
- Simple interface with ‘fly-out’
- The code recognize the document type (so the ribbon can dynamically change to fit different document types)
- One-way flow of information (StudyBuilder -> Word)

Prototype Word add-in

Ribbon



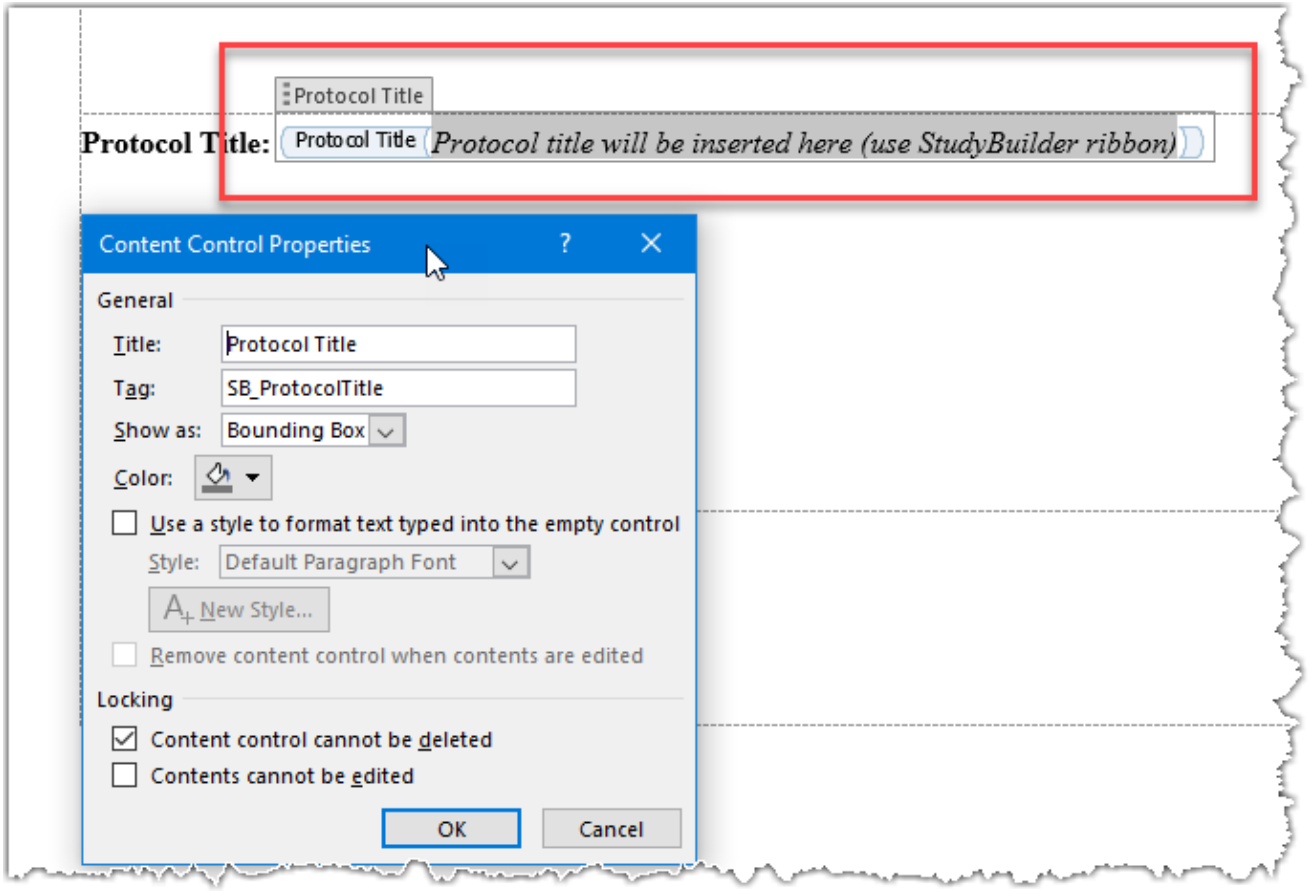
Fly-out



1: Opens fly-out to select a study in StudyBuilder

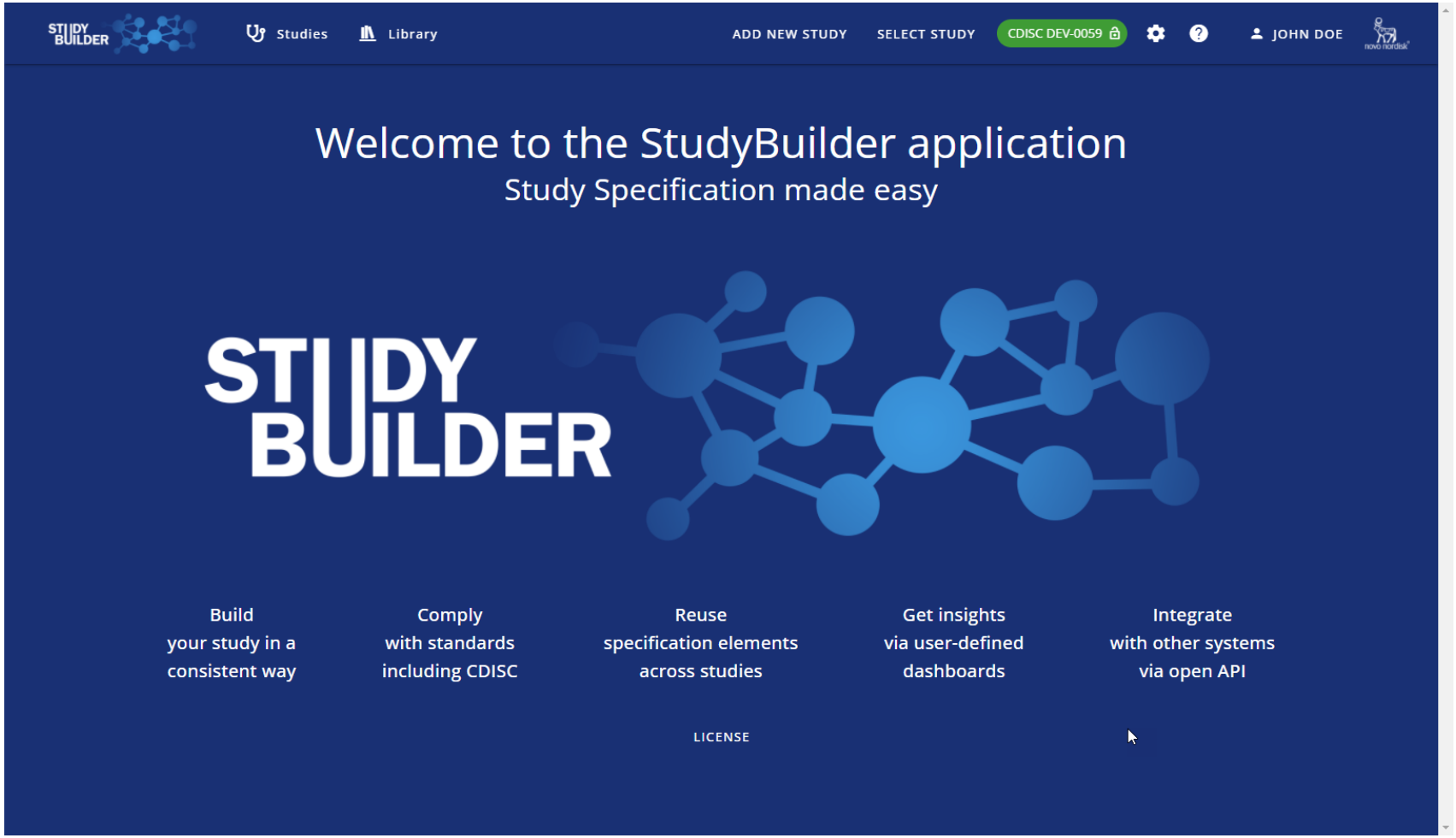
2: Pull information from StudyBuilder to Word doc.

Information flows into Word *Content Controls*

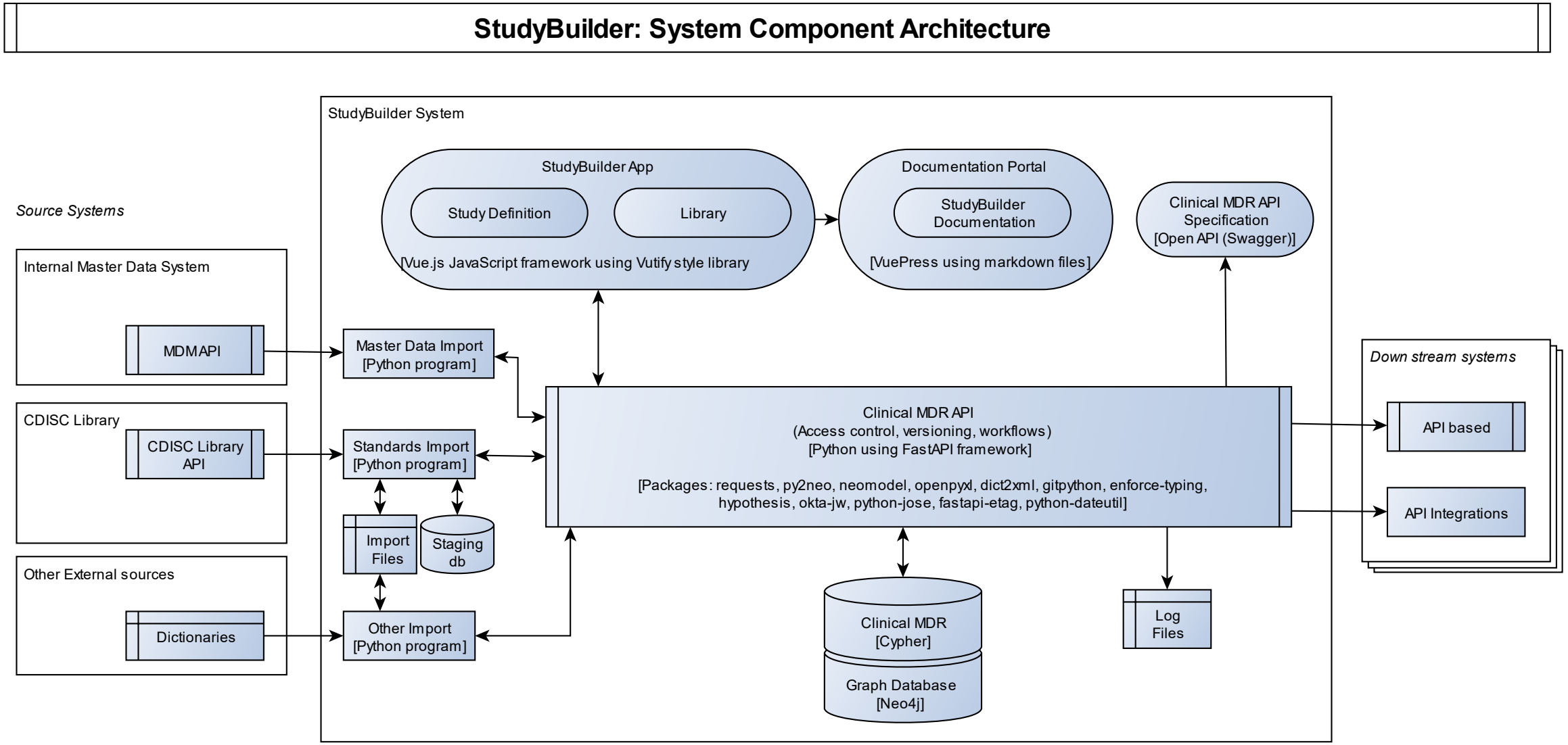


- Concent Control
  = Invisible frame around content
- Great for targeting via code
- Can be locked
- Will be built into template

Live demo


STUDY BUILDER
Studies
Library
ADD NEW STUDY
SELECT STUDY
CDISC DEV-0059
JOHN DOE
Welcome to the StudyBuilder application
Study Specification made easy
STUDY BUILDER
Build your study in a consistent way
Comply with standards including CDISC
Reuse specification elements across studies
Get insights via user-defined dashboards
Integrate with other systems via open API
LICENSE

OpenStudyBuilder integration opportunities



OpenStudyBuilder REST API

Clinical MDR API 1.0 OAS3

/api/openapi.json

Authentication:

Supports OAuth2 Authorization Code Flow, at paths described in the OpenID Connect Discovery metadata document. Microsoft Identity Platform (documentation).

Authentication can be turned off with `OAUTH_ENABLED=false` environment variable. When Authentication is turned on, all API requests have to provide valid bearer (JWT) token. When turned off all endpoints accept (optional) custom header `X-Test-User-Id` which allows any request to inject any user id value (for testing purposes). If the header is missing, the default value of `unknown-user` is assumed.

Servers

/api

ODM Forms

GET	/concepts/odms/forms	Return every variable related to the selected status and version of the ODM Forms
POST	/concepts/odms/forms	Creates a new Form in 'Draft' status with version 0.1
GET	/concepts/odms/forms/headers	Returns possible values from the database for a given header
GET	/concepts/odms/forms/{uid}	Get details on a specific ODM Form (in a specific version)
DELETE	/concepts/odms/forms/{uid}	Delete draft version of ODM Form

Discussion / comments

- Will we continue to use Word..? (Probably not. From a StudyBuilder point of view, Word is just connected down-stream via the API – any future authoring tool could do the same)
- What is the central source of truth? (StudyBuilder vs Protocol)
- StudyBuilder is built as a NN product – which is both a strength and a weakness (NN need it to work – but to not be too NN specific)
- Idea: Author the SAP based on StudyBuilder (already automated in NN?)
- Opportunity: Link templates with algorithms to support downstream processes (check e.g. age ranges against criteria)
- Use a data mining approach to capture e.g. most used / most 'successful' criteria among all protocols?