

“CONNECT and CREATE”

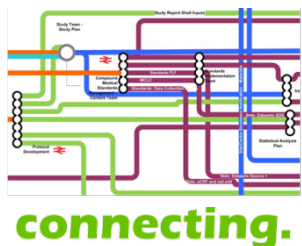
Connect Standards and Enable Protocol Authoring



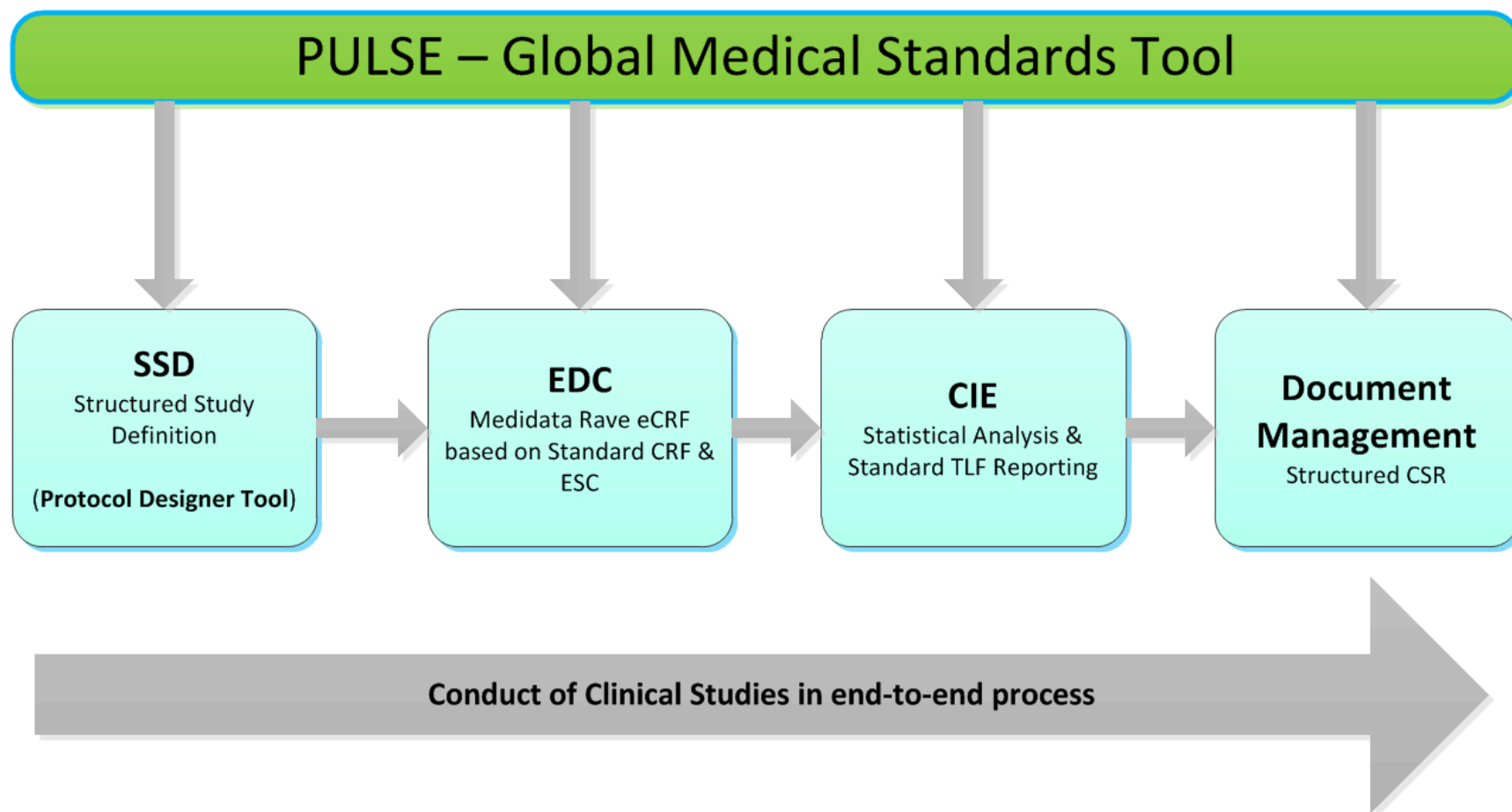
Science For A Better Life

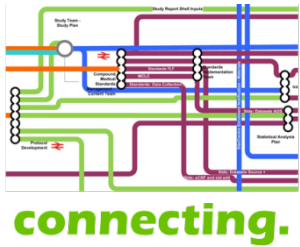
PhUSE Conference 2015, Vienna
Paper DH05

Abi Velurethu
Susanne Pangritz



Our Vision

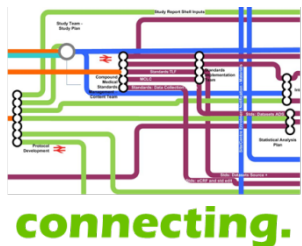




Focus Areas

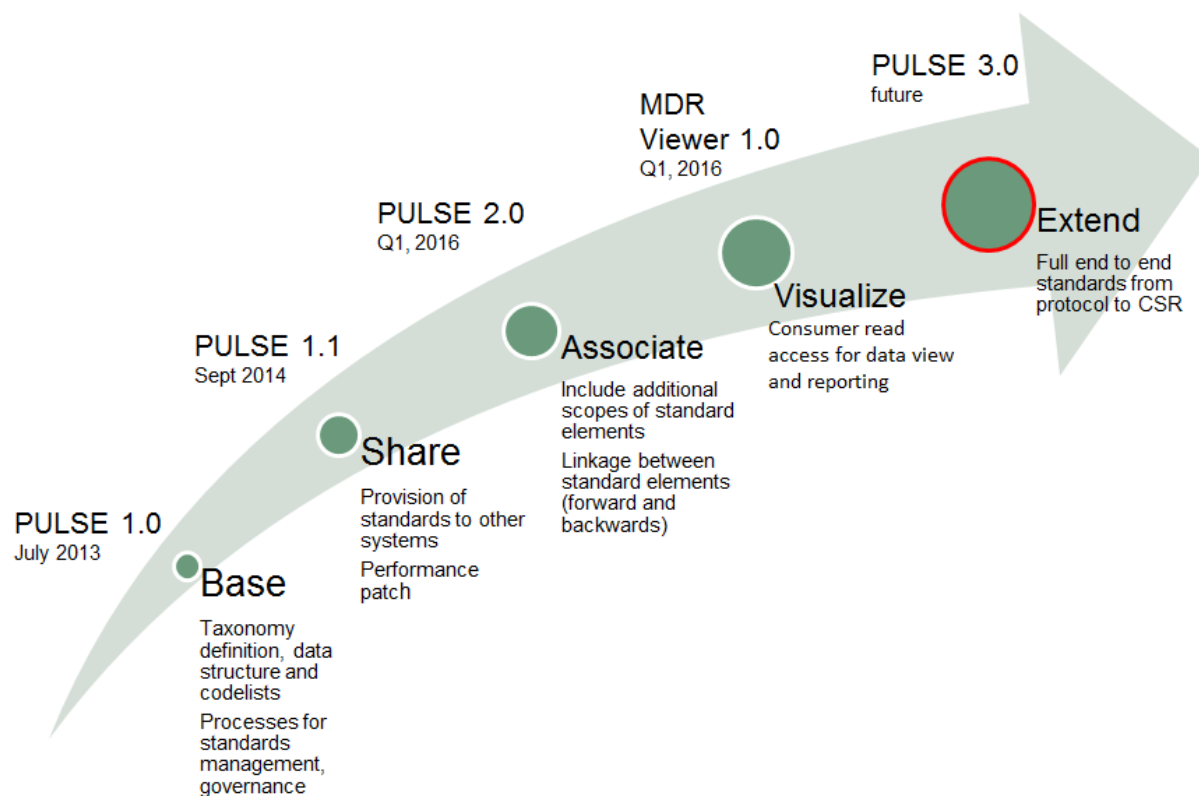
To achieve this vision, Bayer focused on two key areas within the Global Medical Standards toolset initiative:

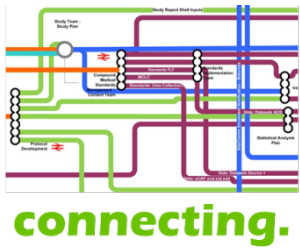
- **Standards Management System**
 - Standards Taxonomy (directory) setup
 - Standards Data Flow
 - Standards Visualization and Reporting
- **Standards Content**
 - Create Standards Content Structure
 - Connect Standards



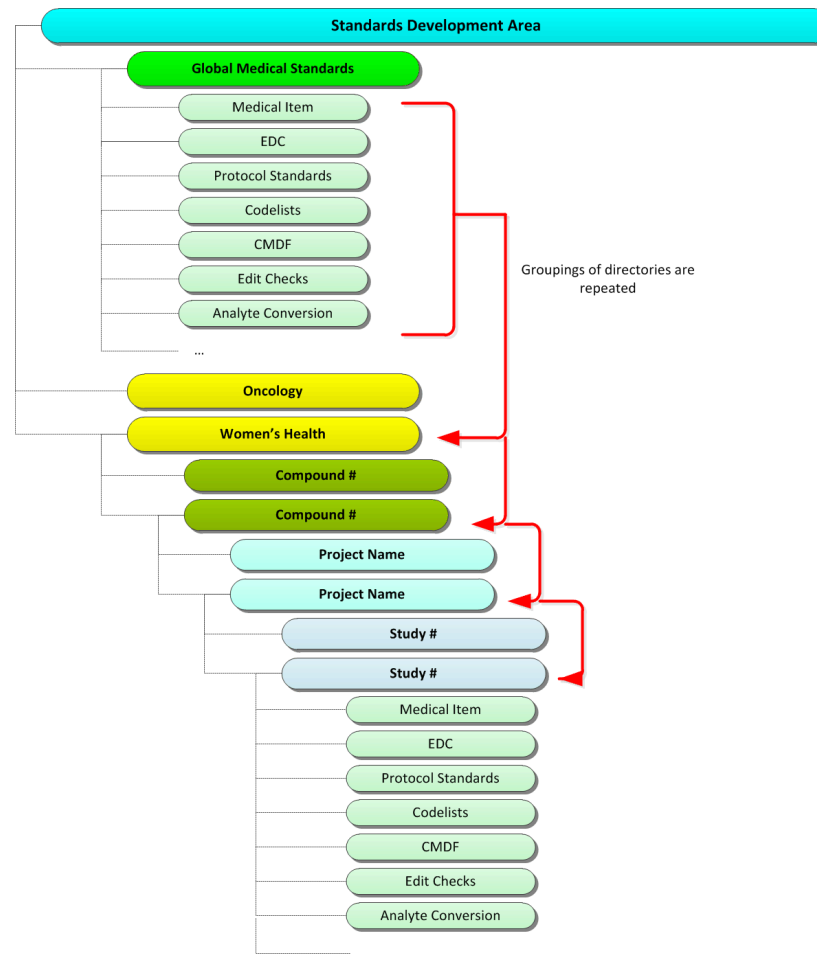
Approach

Phased Approach

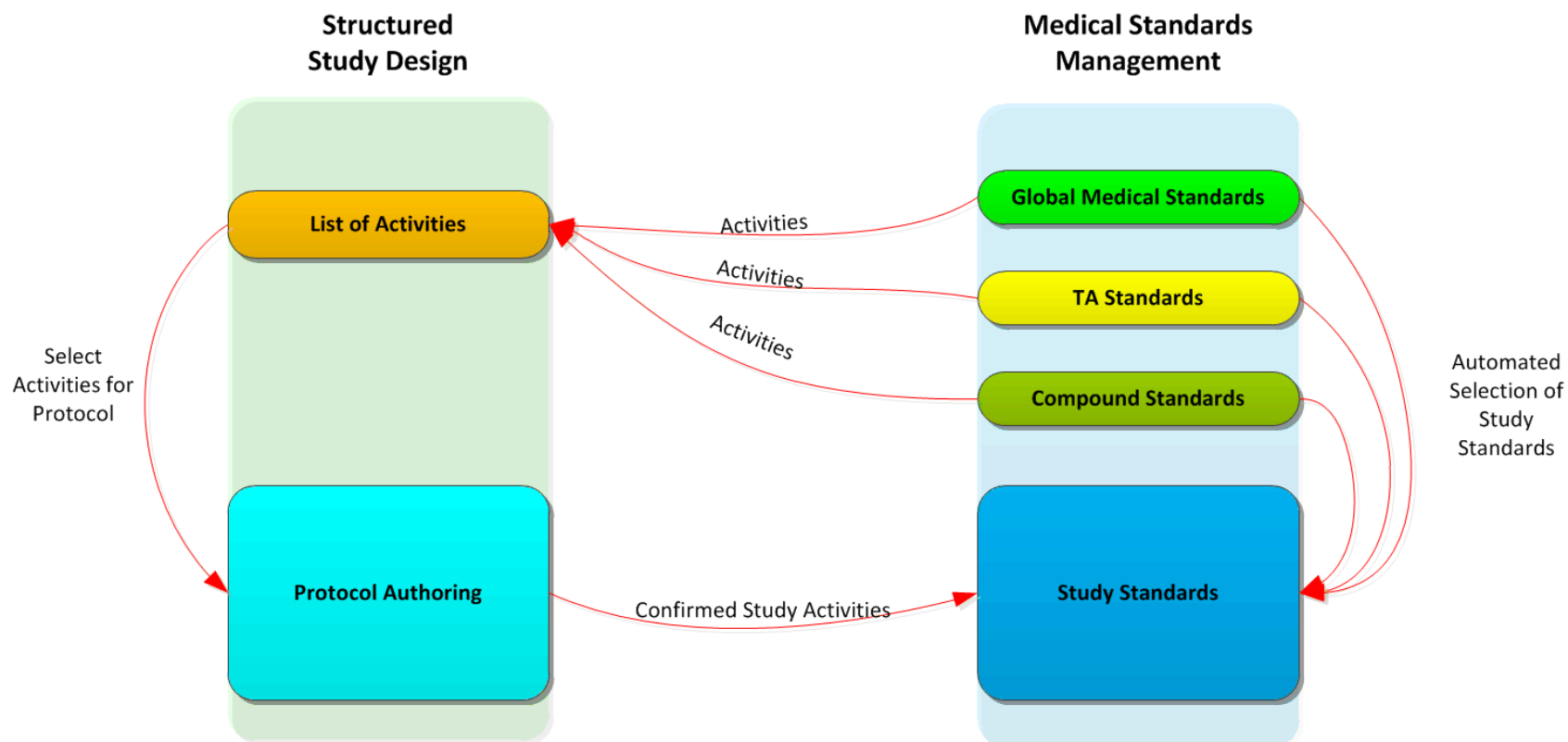


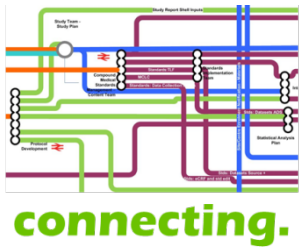


The Structure

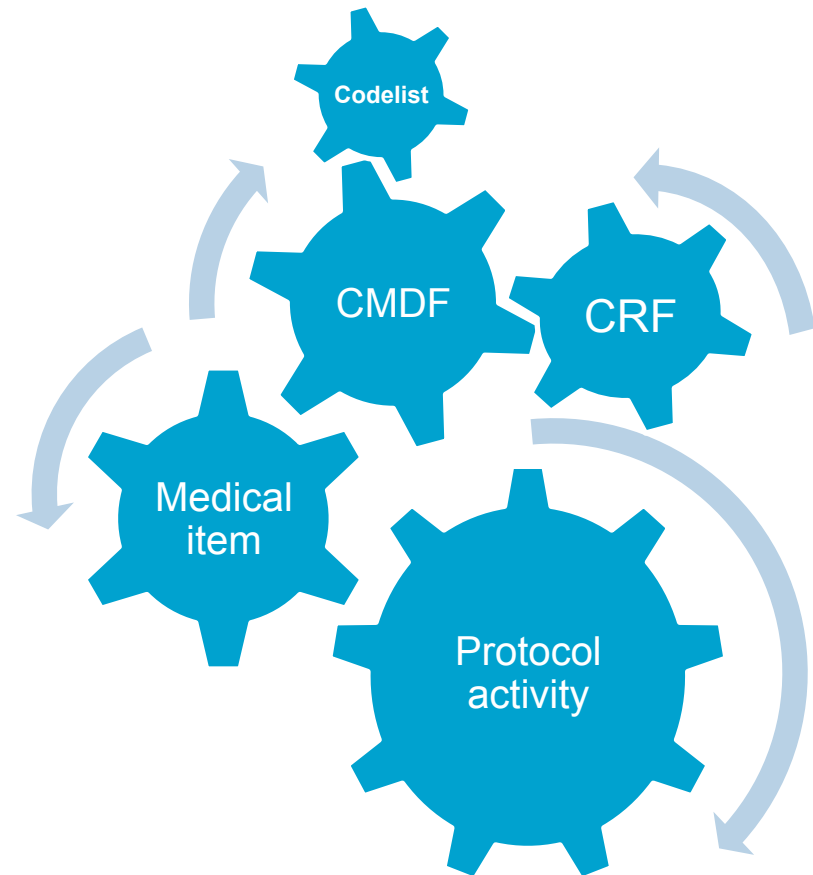
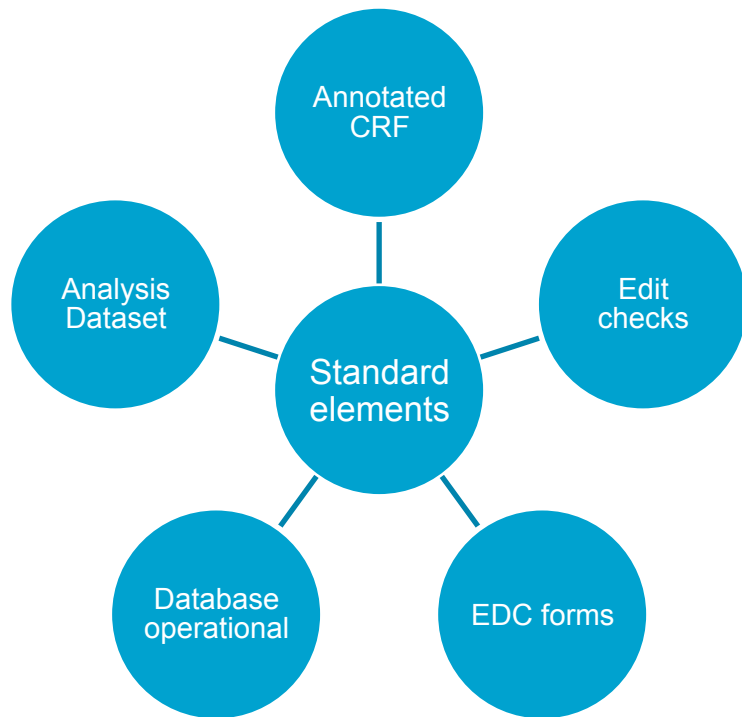


Future State : Connect Activity to Protocol Authoring

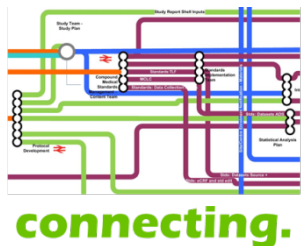




Current – Future situation



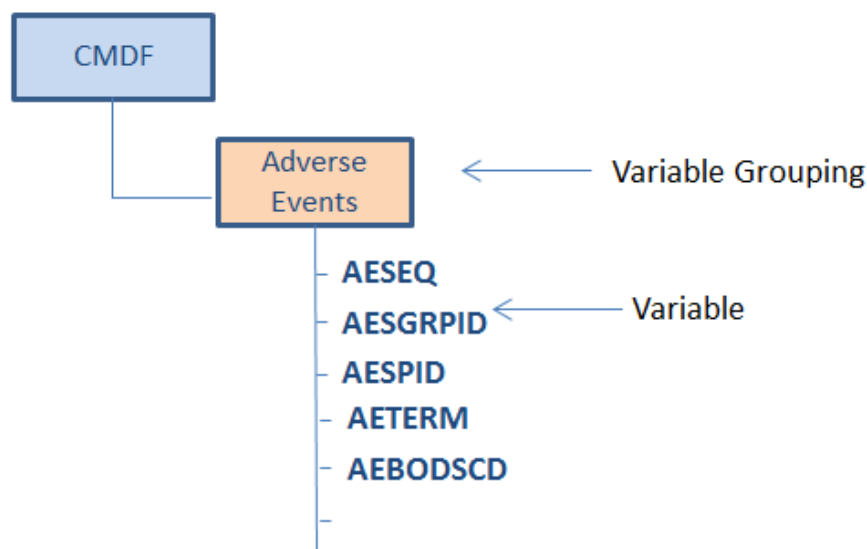
CMDf= Clinical Metadata Foundation

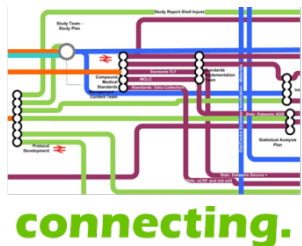


Standard elements – CMDF (1)

Clinical Metadata Foundation (CMDF)

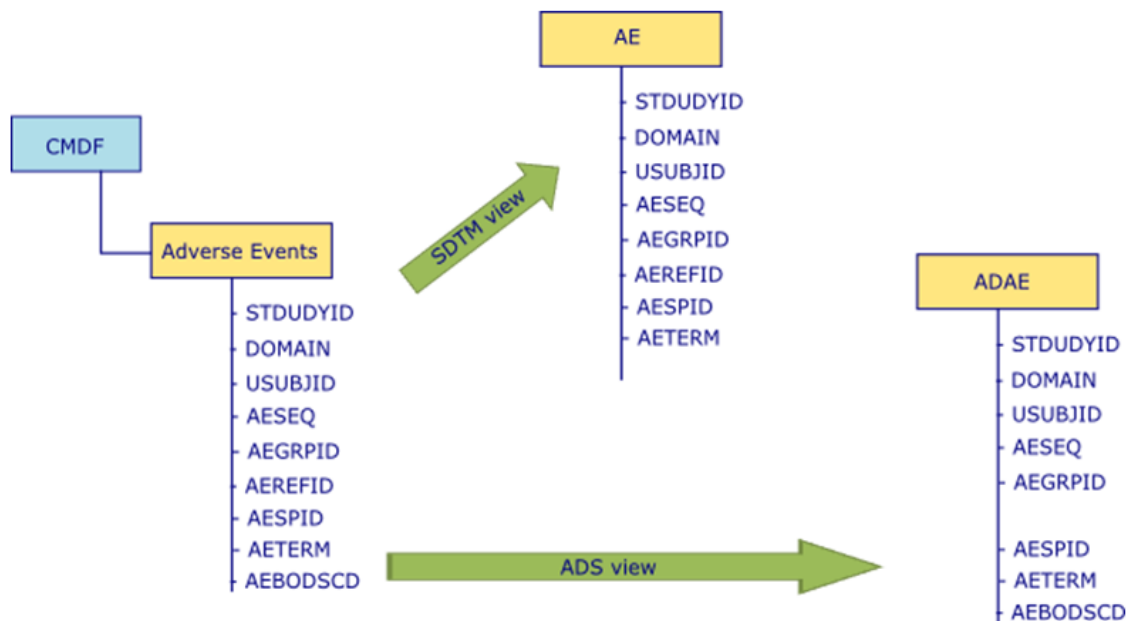
- Superset of all variables and all datasets, grouped according to context
 - Medical topic
 - Common variables

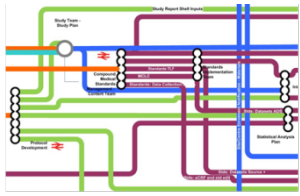




Standard elements – CMDF (2)

- Provide Metadata Structure for different scopes e.g.
 - SDTM
 - ADS
 - Foundation
 - Source plus





connecting.

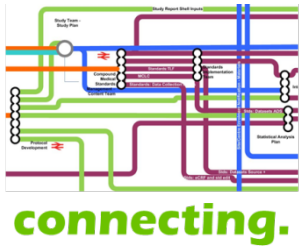
Protocol Activity



Protocol activity

- Describes the activity in a protocol such as the procedure or the measurement performed at the Clinical Research Site to obtain clinical data for the study result.
- Combines medical items and standard protocol text
- Deliverable for standard protocol tool and initiator for complete study set up

Activities Context						
Activity Name	Protocol name	Protocol text	MI Grouping	MI Name	MI Label	
Vital Signs_Brief	Height and Weight	Measure body weight and height (see section 9.6.3).	Vital Signs			
				VS_Date	Date of Vital signs	
				VS_Time	Actual time	
				VS_Height	Height	
				VS_Weight	Weight	
Vital Signs_ex	Vital signs	Measure vital signs (see section 9.6.3).	Vital Signs			
				VS_Date	Date of Vital signs	
				VS_Time	Actual time	
				VS_Height	Height	
				VS_Weight	Weight	
				VS_SYSBP	Systolic Blood Pressure	
				VS_DIABP	Diastolic Blood Pressure	
				VS_PULSE	Pulse Rate	



Standard element

Medical item

- Main driver for linkage of different standard objects
- Developed and maintained by medical team
- Grouped according to medical context
- Reflects data fields on CRF with relevant subset of codes
- Contains medical item specific attributes like CRF label, field help text, implementation instructions
- Has references to CMDF variables and their codelists
- Defines the relevant subset of codelist
- Is used as reference object for protocol activities, e checks and EDC forms

LB Lab

Medical Item: Vendor Name

Medical Item: Planned Time Point

Medical Item: Start date

Medical Item: Start Time

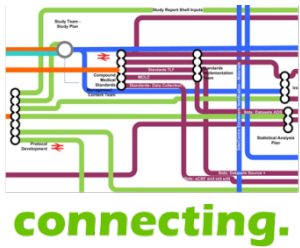
Medical Item: Stop Date

Medical Item: Stop Time

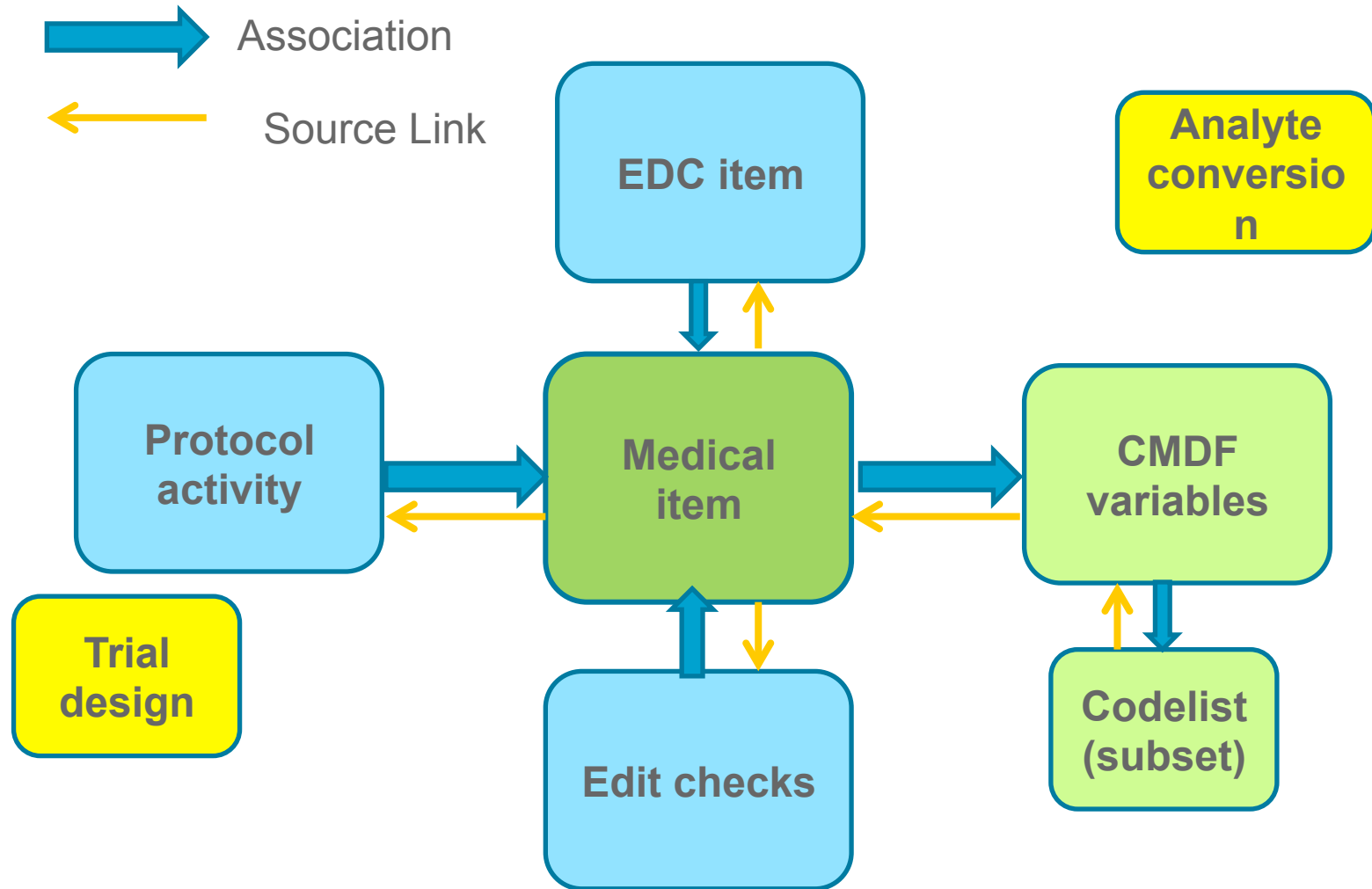
Medical Item: Fasting

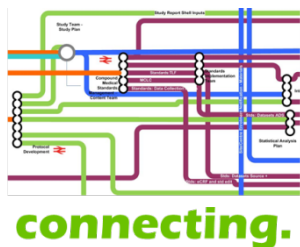
Medical Item: Specimen Condition

Medical Item: Lab Test or Examination

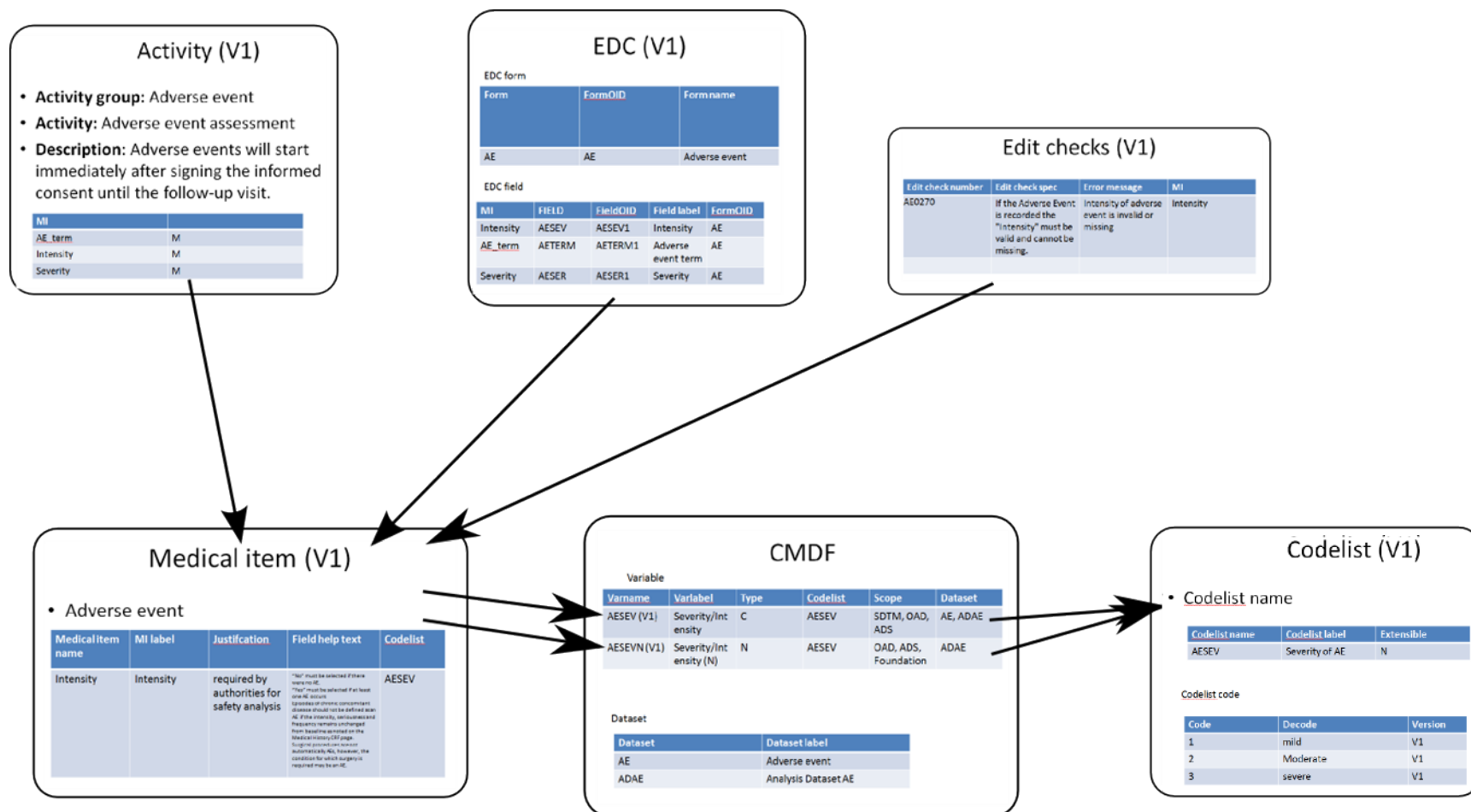


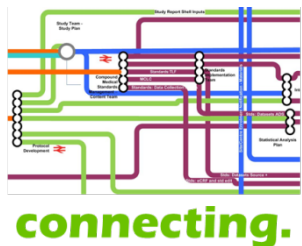
Connect Standards





Example:





Automated study set up

Linked standard objects allow automated study set up:

In other words, selection of **Protocol Activities** will automatically drive the study **standards setup** and provide all standard objects for

Protocol Activities

EDC forms and items

Data base structures

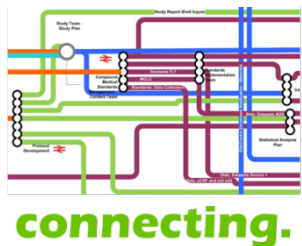
Codelists

Edit checks

Table, Listings and Figure specs

Mappings and derivations

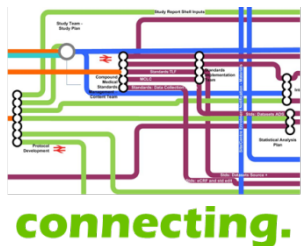
Activity	
Medical items	• Date • Time • Test
Variables	• SDTM variables • ADS variables • ..
Codelist	• Controlled terminology subsets • ADS codelists
Edit checks	
EDC form	



Summary



- Create structure standard objects to enable end to end study set up (Protocol to CSR)
- Consider Standards Hierarchy from Global to Study level
- Build connections between standard elements (forward and backward links)
- Enable flexibility via Metadata supersets
- Allows Standards Maintenance and Governance
- Allows Reporting and Visualization of Standards elements
- Enable automated study set up via referencing protocol activities



Questions?



Thank you,

Susanne Pangritz

Senior Medical Standards Manager

Bayer Vital GmbH

BV-PH-MED-GDS&A-GMS

Leverkusen, K 9, 442

Phone: +49 214 30 51626

Fax: +49 214 30 51285

Cell: +49 175 3051626

Email: susanne.pangritz@bayer.com

Web: <http://www.bayervital.com>

Abi Velurethu

Head, Systems Integrations & Solutions

Bayer HealthCare Pharmaceuticals

100 Bayer Boulevard, PO Box 915

Whippany, NJ 07981-0915

Office Phone: + 1 862 404 3883

Mobile Phone: + 1 215 622 1524

Email: abi.velurethu@bayer.com

Web: <https://pharma.bayer.com>