

# Developing a Medical Meaning Dictionary for Clinical Data

Sam Hume

Alexander Hromcenco

AstraZeneca

## Legacy clinical trial data and business critical needs

The rapidly changing pharmaceutical / biotech industry landscape presents a complex set of Information related challenges, including increased Regulatory Agency scrutiny, a demand for operational efficiency and a greater need to exploit information effectively.

Questions raised by Health Authorities have to be answered timely, accurately, and, primarily, through the review and analysis of clinical trial data.

The area of legacy studies in AstraZeneca presented a significant opportunity for improved data access and increased information transparency to address critical business needs. This opportunity was recognized as of “utmost importance” and the project designed to create the value through quick access to legacy clinical trial data, protecting patients and mitigating immediate risk to AZ portfolio started in 2010.

The launched project adopted highly controlled phased implementation approach to ensure transparency to the business, consistency through all steps and value creation at the end of each phase of the process.

# Business Case for the project

## ● Baseline:

Numerous legacy trials in different locations and formats

Limited transparency in master list / data about clinical trials completed by AZ

Time-consuming access to key data

Lack of comparability for cross-study analysis

## ● Business need:

*"The obligation to know"*

Timely response to regulatory enquiries

Protect revenue and reputation, with a focus on major brands

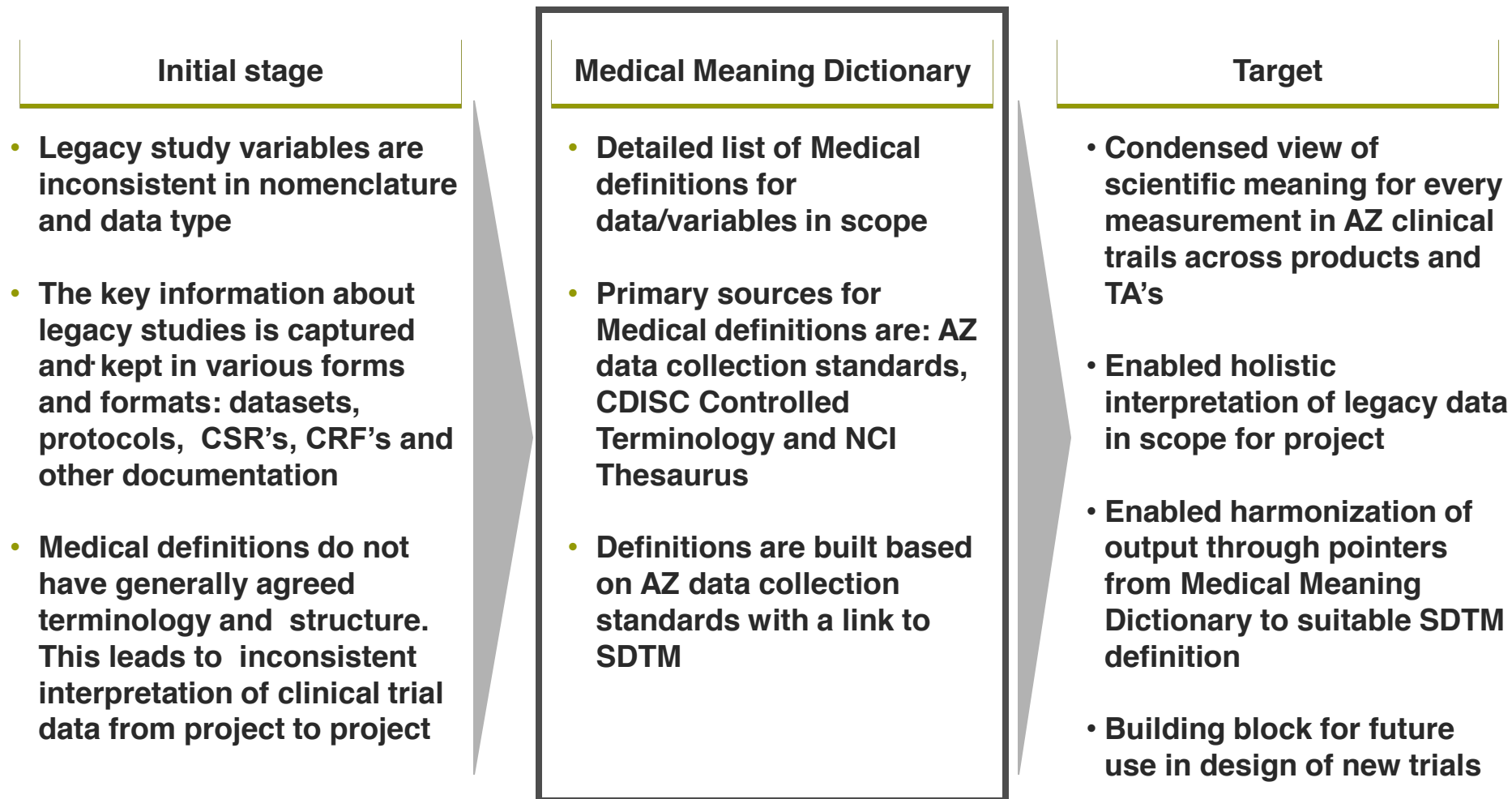
*"Enabling the future"*

Scientific exploitation of data

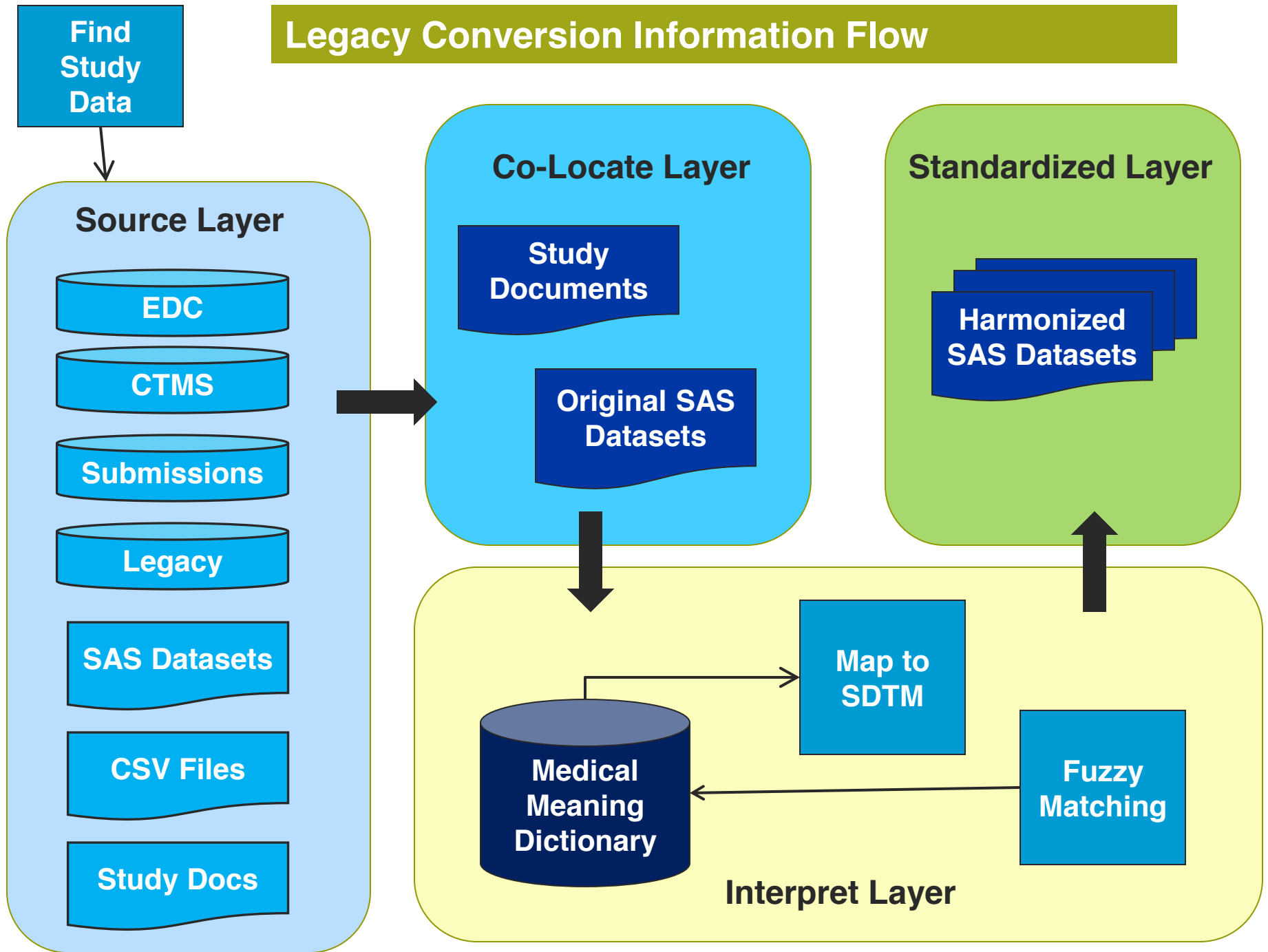
Cross-study analysis of harmonized data

# The Rationale for the Medical Meaning Dictionary creation

The Medical Meaning Dictionary is aiming to support consistent interpretation of legacy and future clinical trial data.



# Legacy Conversion Information Flow



# Medical Meaning Dictionary - Overview

Seed  
Dictionary

Original  
Data Input

Medical  
Meaning  
Dictionary

SDTM  
Mapping

Harmonized  
Output

Raw Data  
Standards

Raw SAS  
Datasets

MM var #1

MM var #2

MM var #3

MM var #4

Variables are defined and added to the Dictionary

SDTM var A

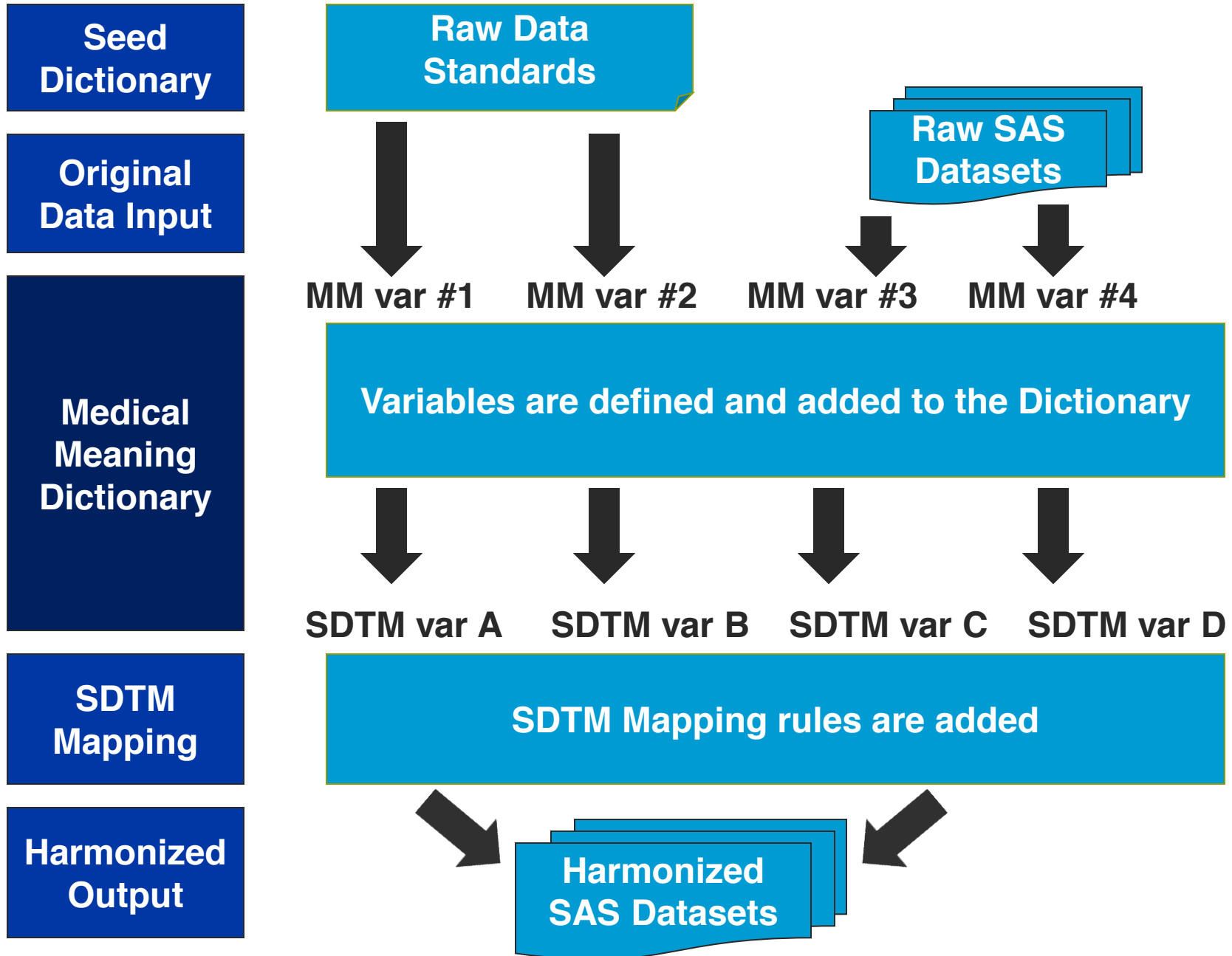
SDTM var B

SDTM var C

SDTM var D

SDTM Mapping rules are added

Harmonized  
SAS Datasets



# Medical Meaning Dictionary – Interpretation

## LEGACY DATASETS

### Study #1

Gndr m  
Temp\_F 98  
Temp\_Meth A  
Pain\_Lev 5

### Study #2

Sex 1  
TEMPER 98.7  
TYPETEMP Oral  
PAT\_PAIN C

### Study #3

PAT\_GEN Female  
Temp\_OR 36.9  
TEMPUNIT C  
PAIN\_NUM 4

## INTERPRET MEANING

### Medical Meaning Dictionary

Find matches

Add aliases

Decompose variables

Assign designation

Find a definition

Assign value lists

Find SDTM information

Study #1  
Mapping rules

Study #2  
Mapping rules

Study #3  
Mapping rules

## HARMONIZED DATASETS

Harmonized  
SAS  
Datasets

# Medical Meaning Dictionary - Contents

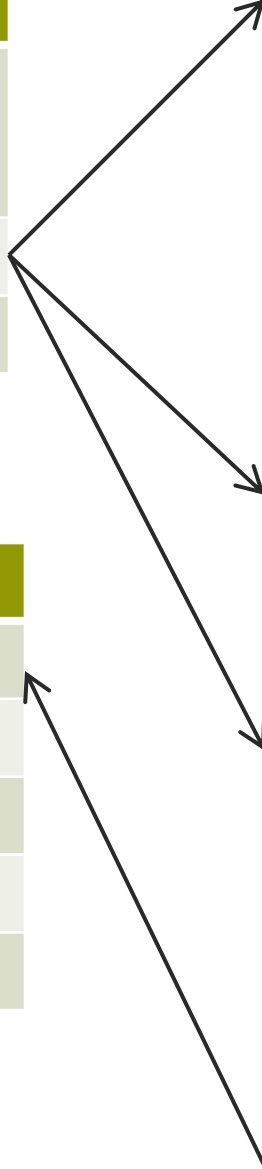
| Field Name         | Example                              |
|--------------------|--------------------------------------|
| Definition         | The rate of the pulse as observed... |
| <b>Designation</b> | Pulse Rate                           |
| Domain             | Vital Signs                          |

| Field Name        | Example     |
|-------------------|-------------|
| <b>Value List</b> | \$UNIT      |
| Valid Values      | 1           |
| Alias Values      | Beats / min |
| Definition        | ...         |
| Units             | Beats / min |

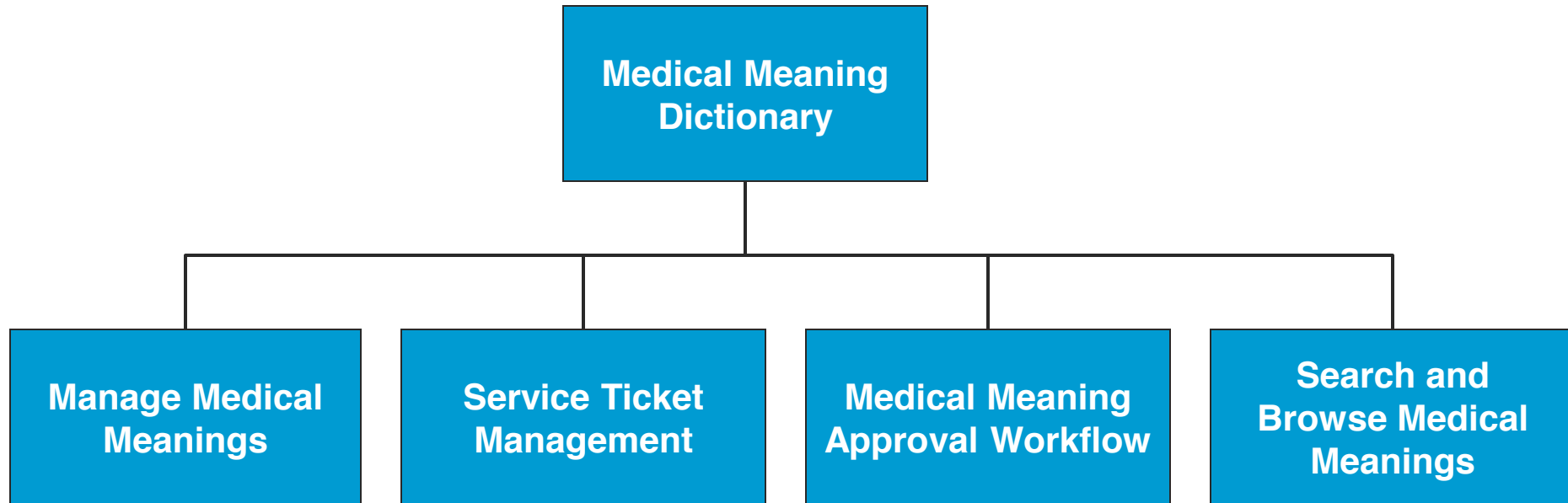
| Field Name           | Example            |
|----------------------|--------------------|
| Definition           | The rate of the... |
| Source               | CDISC ...          |
| <b>Variable Name</b> | PULSE              |
| Variable Label       | Pulse Rate Value   |
| Type                 | NUM                |

| Field Name           | Example       |
|----------------------|---------------|
| <b>Variable Name</b> | POSITION      |
| Alias                | POS, LOCATION |

| Field Name           | Example                |
|----------------------|------------------------|
| Definition           | Unit of measure for... |
| Source               | AZ                     |
| <b>Variable Name</b> | PUNIT                  |
| Variable Label       | Pulse Unit             |
| Value List           | \$UNIT                 |



# Medical Meaning Dictionary - Components



## Medical Meaning Dictionary model - Key Learnings

The existence of defined Clinical Information Strategy, agreed Information Standards and Governance model are critical elements for success.

Experts from various functions are rare resource and their availability has to be secured for the length of the project.

The need for a certain granularity for terms in a Dictionary can be viewed differently from Medical and Information science perspectives.

SDTM is an industry standard with growing recognition and acceptance. SDTM provided common reference and reliable link from theoretical medical definition to harmonized data.

Interpretation of legacy data in SDTM context is time consuming and without care could lead to the creation of SDTM datasets that are not harmonized.

The version control for various clinical data standards and dictionary elements has a raising importance and requires technologies and automated processes to support data alignment.

## Medical Meaning Dictionary model - Next Steps

**Next steps with the use and development of Medical Meaning Dictionary may include:**

Integration of Medical Meaning definition standards into Clinical Information Standards framework. The link to SDTM provides further opportunities for ongoing alignment with industry standards and practices (CDISC).

Further development of Medical Meaning Dictionary terms to cover ongoing studies and not just legacy brands.

The use of Medical Meaning Dictionary to further harmonize legacy data and data for recently completed projects.

Expansion of definitions to incorporate derived elements to support cross-study efficacy analysis.

Support of study design initiatives and advanced information exploitation.

# Questions