

Clinical Research Data Capture (CRD)

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RFD Profile Phases

- **Integration Profile Phase**
 - Define standard format for forms
 - Define standard method for retrieving and submitting forms

- **Content Profile Phase**
 - Provide domain-specific form requirements
 - Enable form population from EHR mapped data

CRD Profile

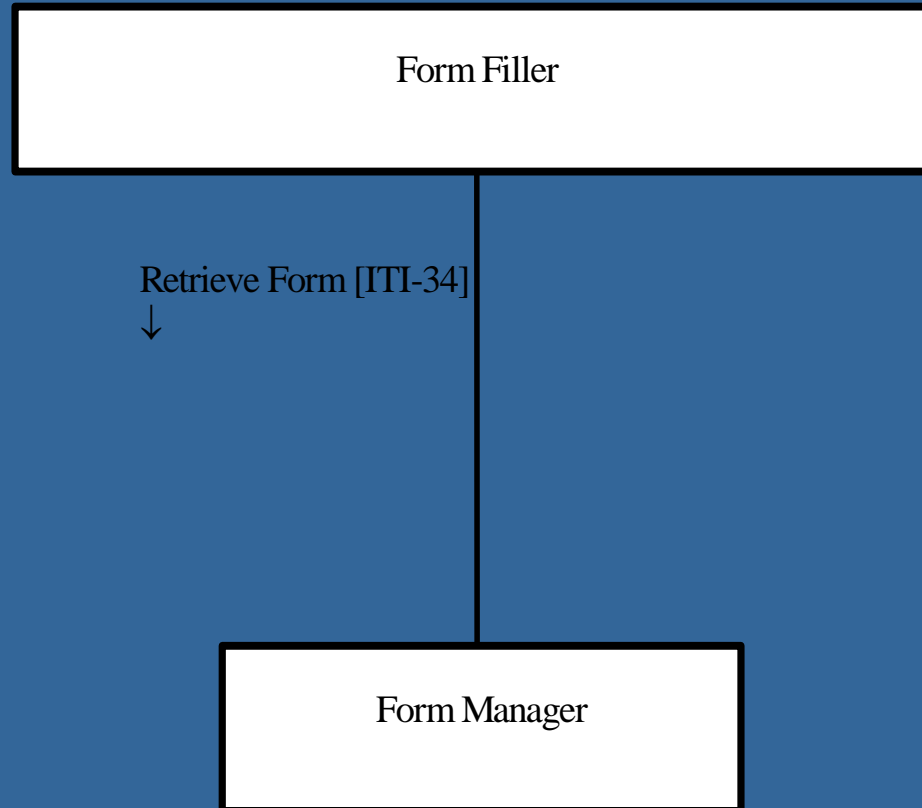
What does CRD do/provide?

CRD describes the content and format to be used within the Prepopulation Data transaction described within the RFD Integration Profile.

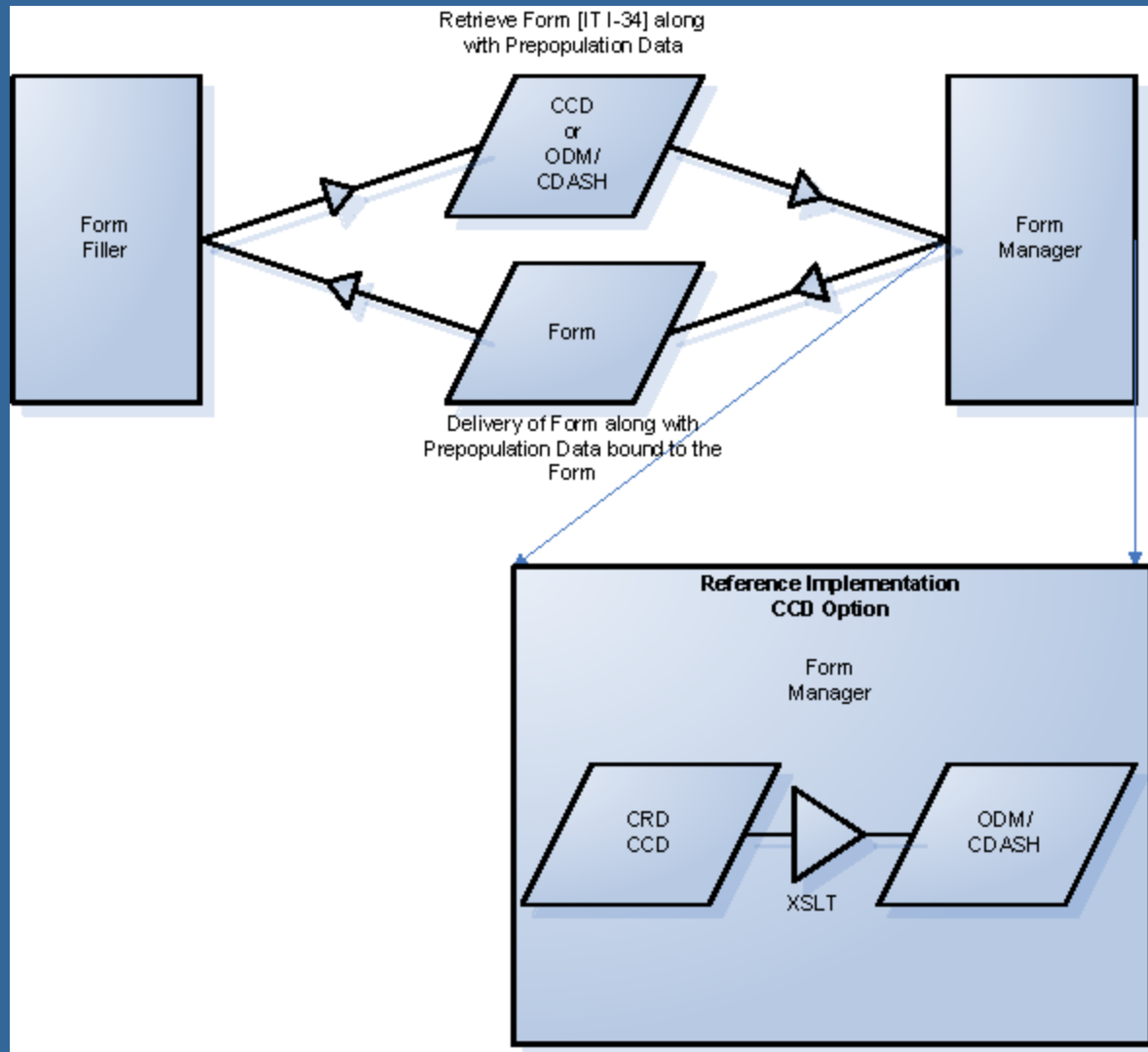
Use Case

- **Investigational New Drug Trials**
 - EHR linked to pharma sponsor via EDC
 - EHR makes accessible the basic data collection variables
 - EHR request an electronic case report form
 - Physician completes and returns the electronic case report form to the EDC system

Actors and Transactions



Process Flow



CRD Actors/Options

- **Form Filler: An actor for retrieving Forms**

PrepopData Options:

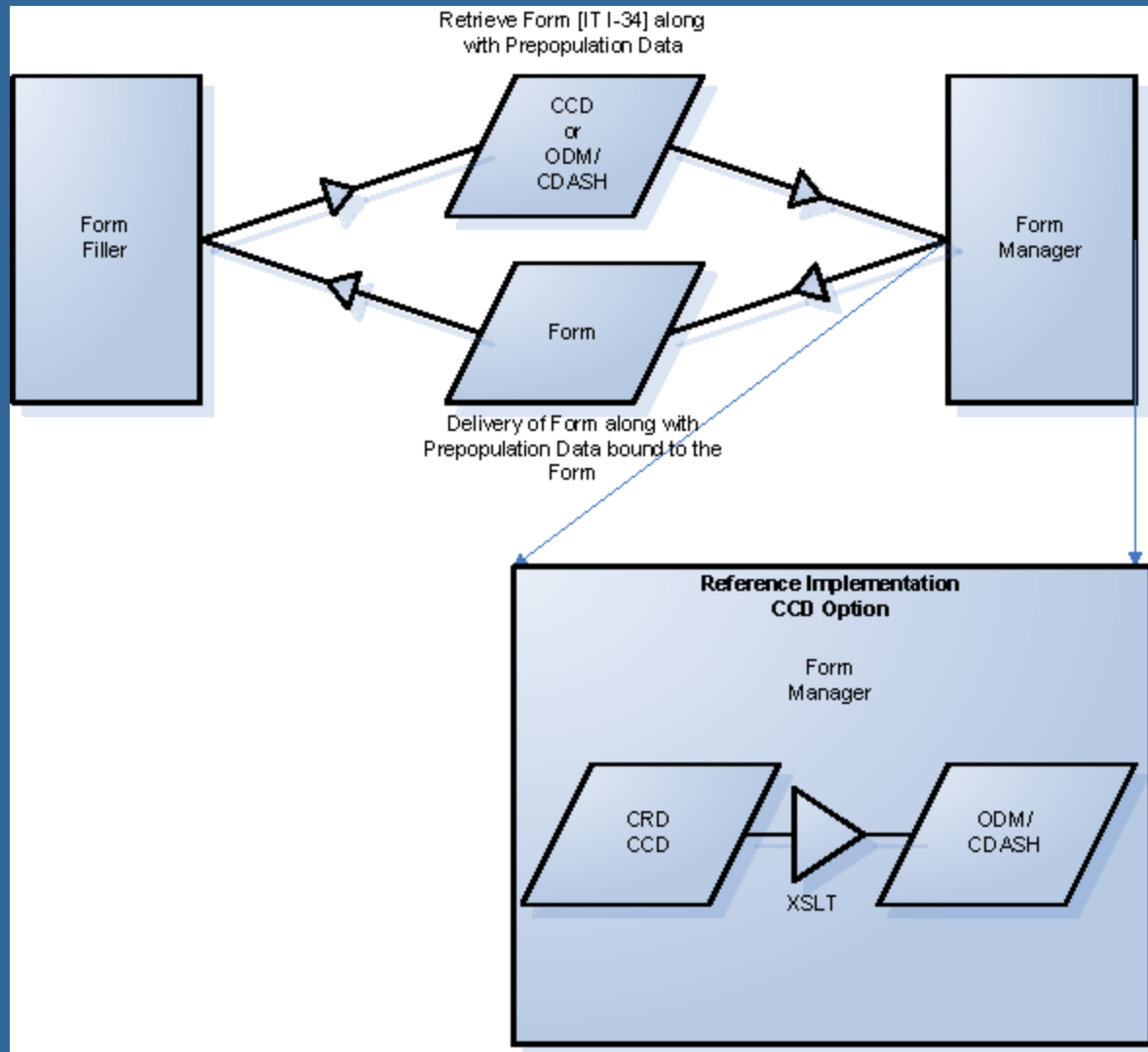
- CCD Option
- ODM/CDASH Option

- **Form Manager: An actor for supplying Forms**

PrepopData Options:

- CCD Option
- ODM/CDASH Option

Process Flow



CCD Option

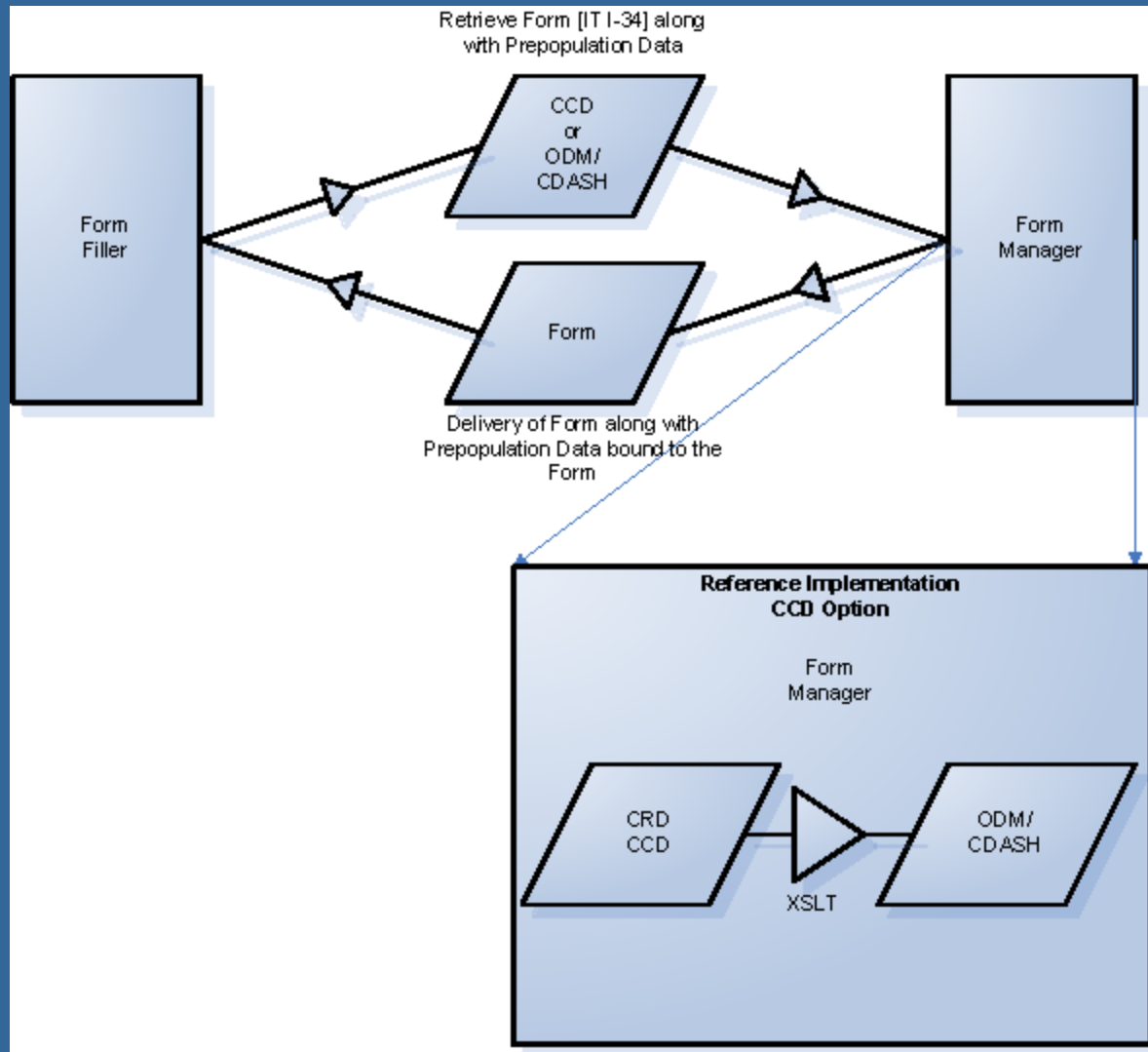
Clinical Research Data Capture Constraints (CCD Option)		
Data Element	Optionality	Template ID
Date of Birth	R	patientRole/patient/birthTime
Gender	R	patientRole/patient/administrativeGenderCode
Ethnicity	O	patientRole/patient/ethnicGroupCode
Race	R2	patientRole/patient/raceCode
Active Problems	R	<u>1.3.6.1.4.1.19376.1.5.3.1.3.6</u>
Past Medical History	R2	<u>1.3.6.1.4.1.19376.1.5.3.1.3.8</u>
Procedures and Interventions	R2	<u>1.3.6.1.4.1.19376.1.5.3.1.1.13.2.11</u>
Social History	R2	<u>1.3.6.1.4.1.19376.1.5.3.1.3.16</u>
Current Medications	R	<u>1.3.6.1.4.1.19376.1.5.3.1.3.19</u>
Vital Signs	R2	<u>1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2</u>
Physical Exam	R2	<u>1.3.6.1.4.1.19376.1.5.3.1.1.9.15</u>
Allergies and Other Adverse Reactions	R	<u>1.3.6.1.4.1.19376.1.5.3.1.3.13</u>
Coded Results	R2	<u>1.3.6.1.4.1.19376.1.5.3.1.3.28</u>

ODM/CDASH Option

CDASH - Clinical Data Acquisition Standards Harmonization (Draft) ODM - Operational Data Model Final Version 1.3

Clinical Research Data Capture Constraints (CDASH Option)			
CDASH Domain	Clinical Database Variable Name	Optionality	Definition
Demography	BRTHYR	R	Year of subject's birth.
	BRTHMO	R	Month of subject's birth.
	BRTHDY	R2	Day of subject's birth.
	BRTHTM	O	Time of subject's birth,
	SEX	R	The assemblage of physical properties or qualities by which male is distinguished from female; the physical difference between male and female; the distinguishing peculiarity of male or female. (NCI – CDISC Definition).

Process Flow



CRD Reference Implementation

- **Clinical Research CCD to Standard CRF (ODM/CDASH) Crosswalk**
 - **XSLT**
 - The adopted format for this transformation
 - **Additional Use Cases to drive different flavors of transformations**
 - **Maintain source control and facilitate sharing and updating**



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