Computable Case Reporting for Multicenter Clinical Trials and Registries King AJ, Malakouti S, Music E, Kalchthaler K, Holton J, Quinn K, Clermont G, Marroquin O, Angus DC, Horvat C

Background & Current State

Case Report Forms (CRFs)

- Objective: to preserve and maintain quality and integrity of data*.
- Paper or electronic
- Standardized to address the needs of all users
- Investigators, data entry personnel, medical coder and statisticians, etc.

Conventional CRFs are completed by manual data abstraction

Data collection costs scale linearly with # of patients

Automated CRF

- Data abstraction from electronic health records (EHR) using programmed queries.
- Could improve: Efficiency, Accuracy, Reproducibility, Auditability

Barriers to automated CRF

- EHR systems lack interoperability.
- Data collection schemas may not match what data are electronically recorded.
- Data completion guidelines may not be precise enough for non-clinician software programmers to implement.

Figure 1. An example CRF. This screenshot is from the World Health Organization's Global COVID-19 Clinical Platform.

World Health	
Organization	PARTICIPANT ID ² II II II II II I
Module 1: Background demographical and epidemiological information	
This module is completed by patient caregiver (in case of children) health care worker	
Facility name of follow up visit (if applies)	Country
Date of module 1 completion: [D_][D_]/[M_][
1.1 Acute episode of COVID-19 information (first episode, in case of re-infection)	
Does the patient have a WHO Rapid Core CRF	•
If Yes, report PARTICIPANT ID of CORE CRF	
1.2 Demographics	
Sex at Birth: Male Female Not specified	
Age: [][][] years; OR [][] months [][] day	/s
Height (Length): [][] cm	
Weight: [][][] kg	
Highest level of education completed? No	
Elementary school Vocational school Secondary school University In the last 3 years, has the participant ever stayed overnight in a hospital, rehabilitation fac	
	Yes, a rehabilitation facility Yes, a long-term car
All No Unknown	res, a tenabilitation lacinty res, a long-term car
	resident prior to initial COVID-19 diagnosis?
Yes No Unknown	······································
Ethnicity/background: Asian Black White	e Mixed Arab Latino Other Unknown
Smoking: Current Former Never Unkno	
Substance abuse: Yes No Unknown; If yes: Alcohol Drug Other	
	are worker or laboratory staff since Jan 1st, 20
Yes No Unknown Pregnancy information	
	illness of COVID-19? Yes No Unknown; If ye
weeks at COVID-19 diagnosis/clinical suspicion	
If pregnant during the acute illness, outcome of	of pregnancy? Miscarriage Induced abortion
Live birth Still pregnant;	
<pre>[] [] weeks;</pre>	ntly not pregnant: gestational age at the time of o
If delivered, mode of delivery? Vaginal Ass	isted vaginal Caesarean section:
Is the participant currently pregnant? Yes	No Unknown; If yes, gestational weeks [][]W
If recently pregnant, is the participant currently breastfeeding? Yes No Unknown	
1.3 Pre-existing conditions in the year prior to your acute illness of COVID-19:	
	D-19, has the participant been diagnosed with
following conditions?	
Asplenia:	Yes No Unknown;
Cancer:	Yes No Unknown;
Chronic heart disease (not hypertension):	Yes No Unknown;
Chronic kidney disease: Chronic liver disease:	Yes No Unknown; Yes No Unknown;
Chronic lung disease:	Yes No Unknown;
Chronic neurological disorder:	Yes No Unknown;
If Yes, specify:	Dementia Stroke Multiple Sclerosis Parkins
Diabetes:	Yes No Unknown;

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acility, are facility

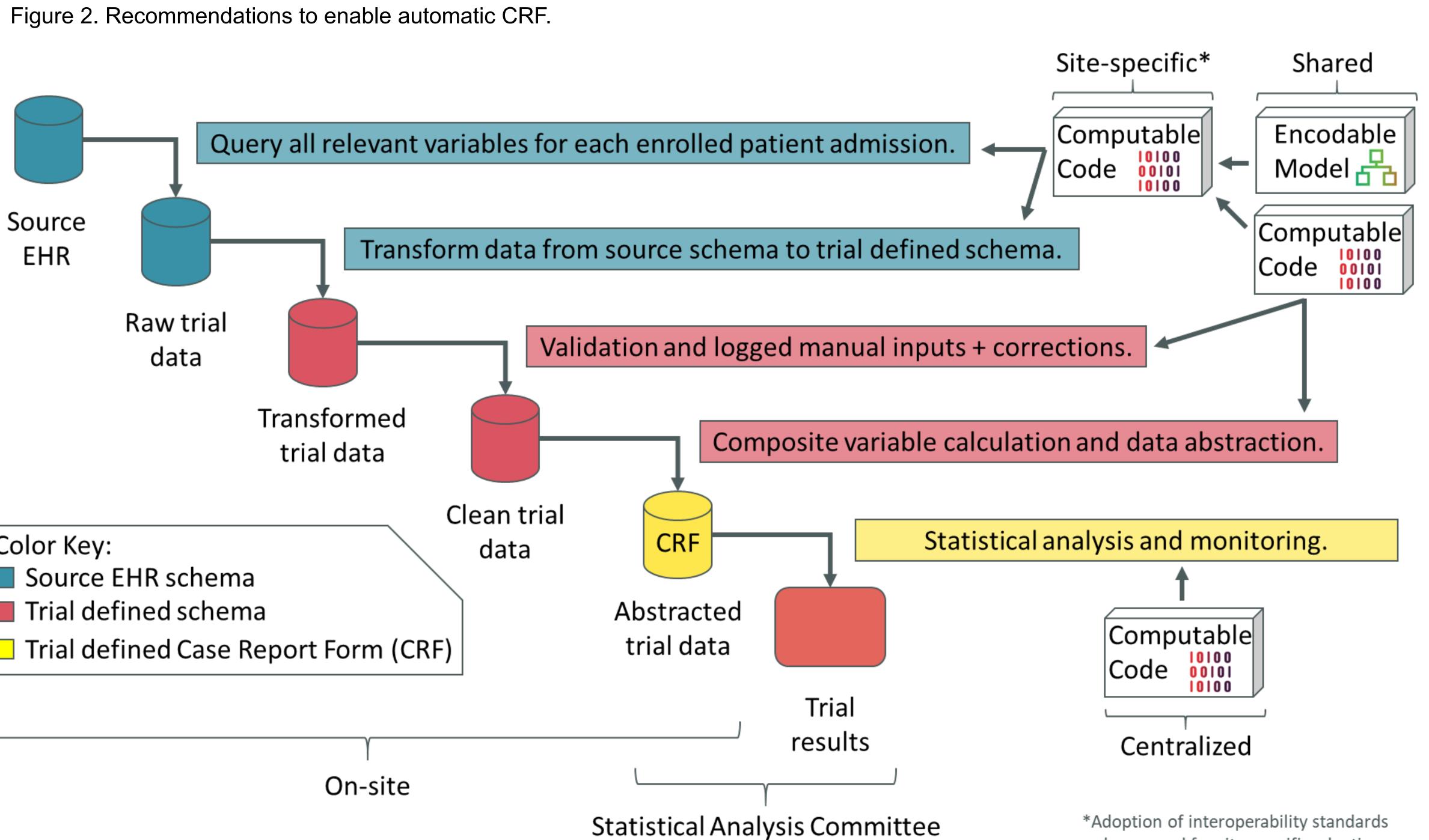
2020?

yes, gestational Still birth f delivery/abortion?

Weeks Unknown;

h any of the

son's Disease;



Color Key: Source EHR schema Trial defined schema



Future State



reduces need for site-specific adaption