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STREAMLINING DATA COLLECTION AND FLOW FOR CENTRAL UNITS IN LARGE MULTI-CENTER CLINICAL TRIALS

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SCT- May 23, 2012

OVERVIEW

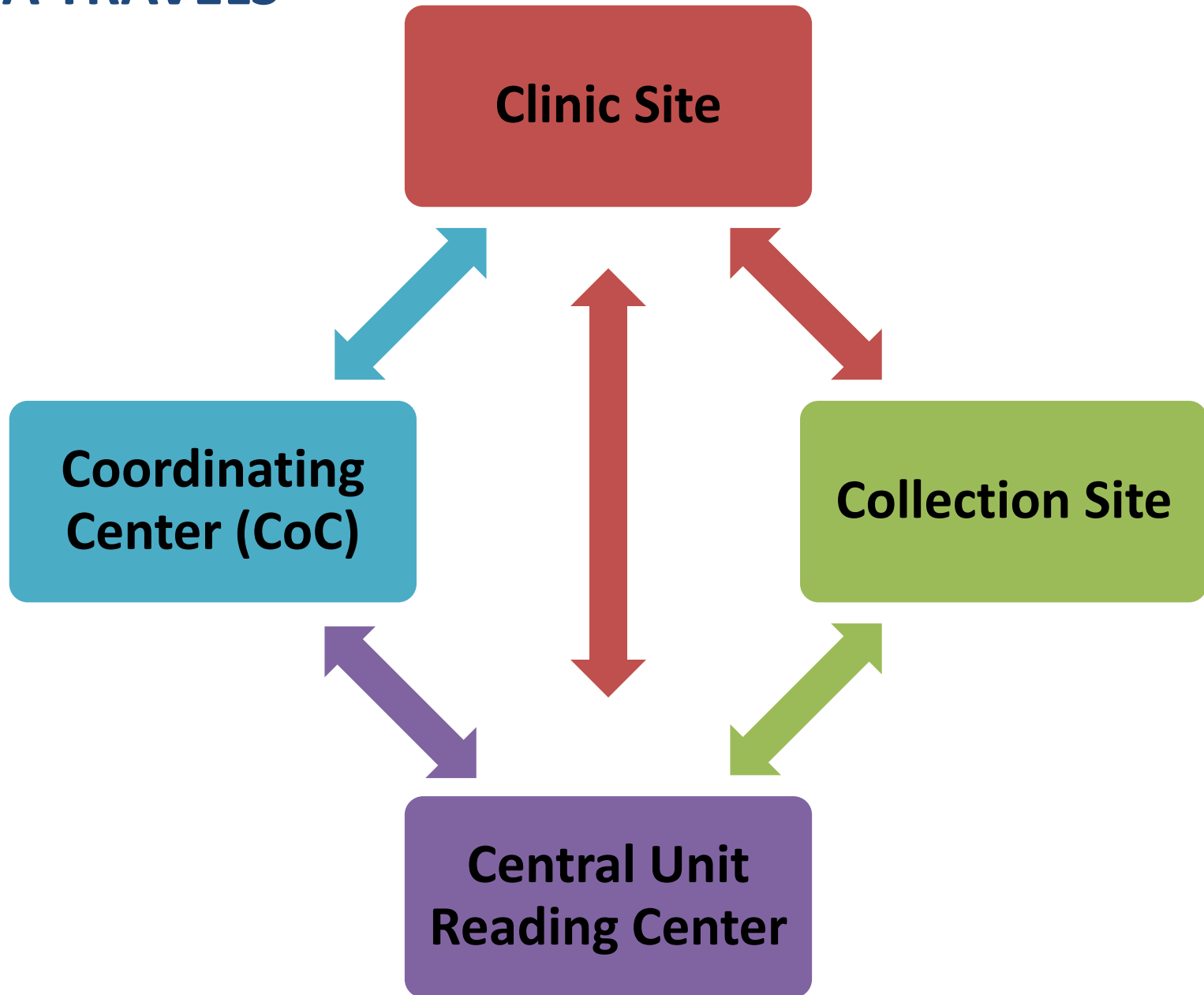
- **The data pathway**
- **Streamlining the pathway**
- **Suggestions**

The slide features a dark blue background with a vertical gradient of lighter blue stripes on the left side. Several blue circles of varying sizes are scattered on the left, with the largest one at the top left and others below it. The text 'THE DATA PATHWAY' is centered in the lower half of the slide.

THE DATA PATHWAY

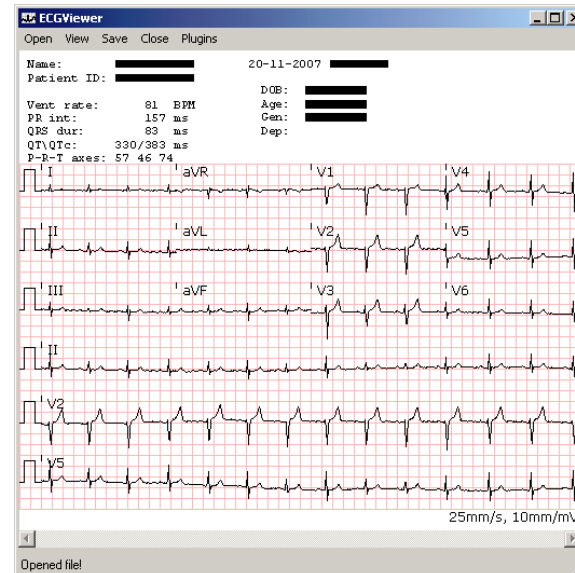
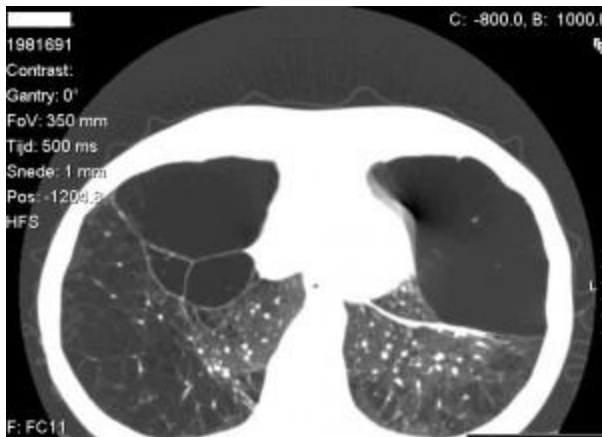
3

DATA TRAVELS



EXAMPLES OF CENTRAL UNITS

- Biochemistry labs
- Retinal photograph reading center
- CT scan reading center
- DEXA scans reading center
- Electrocardiographs reading center
- Paper form self-administered questionnaire reading centers etc.



The slide features a dark blue background with a vertical gradient of lighter blue stripes on the left side. Several blue circles of varying sizes are scattered on the left, with the largest one at the top left and others below it. The text 'STREAMLINING THE PATHWAY' is written in white, bold, uppercase letters on the right side of the slide.

STREAMLINING THE PATHWAY

6

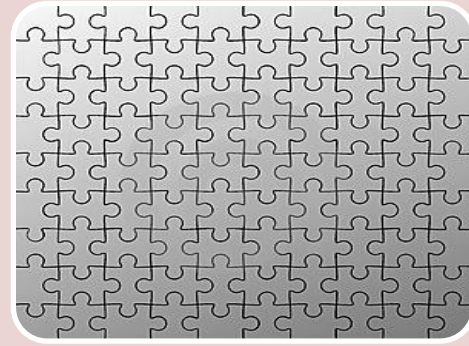
GOALS



Accuracy



Consistency






**Complete
assessments**

HOW? STREAMLINE STEP BY STEP

1. **Plan participant flow from Clinical Site → Collection Site**
2. **Develop data flow from Collection Site → Reading Center**
3. **Develop secure data transfer from Reading Center → CoC**
4. **Develop data validation methods for incoming Reading Center data → CoC**
5. **Develop process reporting safety alert values to Clinical Sites**

STREAMLINE STEP BY STEP

1. **Plan participant flow from**   
2. Develop data flow from Collection Site → Reading Center
3. Develop secure data transfer from Reading Center → CoC
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CREATE STANDARDIZED FLOW



1. Clinic assesses participant eligibility



2. Clinic obtains participant consent



3. Clinic schedules participant appointment



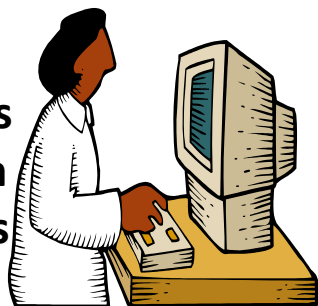
4. Clinic sends data form to collection site



5. Participant examination



6. Collection site sends data to Clinic & Central Unit



7. Clinic completes data form and sends to CoC

STREAMLINE STEP BY STEP

1. Plan participant flow from Clinical Site →
Collection Site

2. **Develop data flow from**

Collection
Site



Central Unit
Reading
Center

3. Develop secure data transfer from Reading
Center → CoC

4. Develop data validation methods for incoming
Reading Center data → CoC

5. Develop process reporting alert values to
Clinical Sites

POSSIBLE DATA FLOW METHODS



Courier Services



Transmission Software



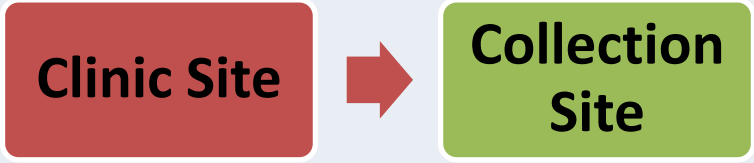

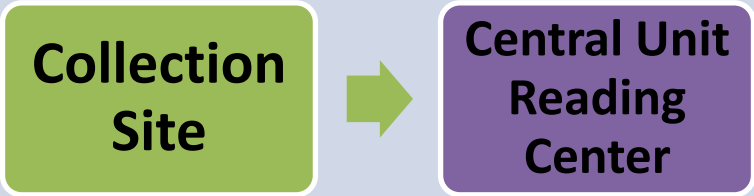
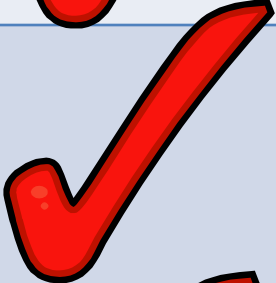

Web-based Portals

COMPARING DATA FLOW METHODS

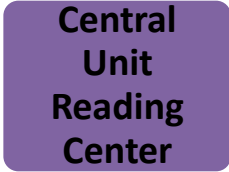
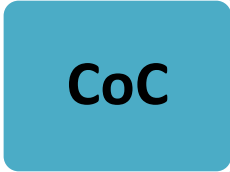
	COURIER SERVICES	TRANSMISSION SOFTWARE	WEB-BASED PORTAL
EXAMPLE	<ul style="list-style-type: none"> • FedEx 	<ul style="list-style-type: none"> • DICOM Push 	<ul style="list-style-type: none"> • Online portal
PROS	<ul style="list-style-type: none"> • User friendly • Good for physical samples 	<ul style="list-style-type: none"> • Speed • Cost 	<ul style="list-style-type: none"> • Speed • Tracking ability • Real time updates
CONS	<ul style="list-style-type: none"> • Cost • Time • Not “green” 	<ul style="list-style-type: none"> • Initial set up • Staff training • Fall back method • No physical samples 	<ul style="list-style-type: none"> • Need portal support • Upload time dependent on internet speed • Fall back method • No physical samples

AFTER STEPS 1 & 2 HAVE BEEN DEVELOPED...

PILOT COLLECTIONS CAN BE HELFUL IN:

TESTING FLOW	 <pre>graph LR; A[Clinic Site] --> B[Collection Site]</pre>	
TESTING FLOW	 <pre>graph LR; A[Collection Site] --> B[Central Unit Reading Center]</pre>	
CERTIFICATION OF STAFF OR EQUIPMENT		

STREAMLINE STEP BY STEP

1. Plan participant flow from Clinical Site → Collection Site
2. Develop data flow from Collection Site → Reading Center
3. **Develop secure data transfer from**  → 
4. Develop data validation methods for incoming Reading Center data → CoC.
5. Develop process reporting alert values to Clinical Sites

PREAPPROVED FORMATS

DESCRIPTION	FORMAT	EXAMPLE
Date of collection, receipt, analysis	mm/dd/yyyy	04/12/2012
Analyzed by	First initial, Last name	pmangat
Sample name	Study name, participant ID -----	ABC 123456

- Consistency
- Accuracy
- Helpful in data editing

UNIQUE IDENTIFIERS FOR VARIABLES

DESCRIPTION	VARIABLE LABEL	RANGE OR POSSIBLE VALUE
Total coronary artery calcium volume score (HU)	TOTCAC_VS	0-10,000
Retinopathy severity level for the eye recoded as an integer	GRDRSEVREC	1-12

- Ranges, possible values especially helpful in editing unfamiliar measurements

STREAMLINE STEP BY STEP

1. Plan participant flow from Clinical Site → Collection Site
2. Develop data flow from Collection Site → Reading Center
3. Develop secure data transfer from Reading Center → CoC

4. **Develop data validation methods for incoming data from**

Central Unit
Reading Center



CoC

5. Develop process reporting alert values to Clinical Sites

CHECKLIST FOR INCOMING CENTRAL UNIT DATA

STEP 1

Does the participant exist in the base record?



STEP 2

Does the assessment date match corresponding study form date?



STEP 3





Does every observation on the assessment have a corresponding entry in the list of preapproved variable labels?



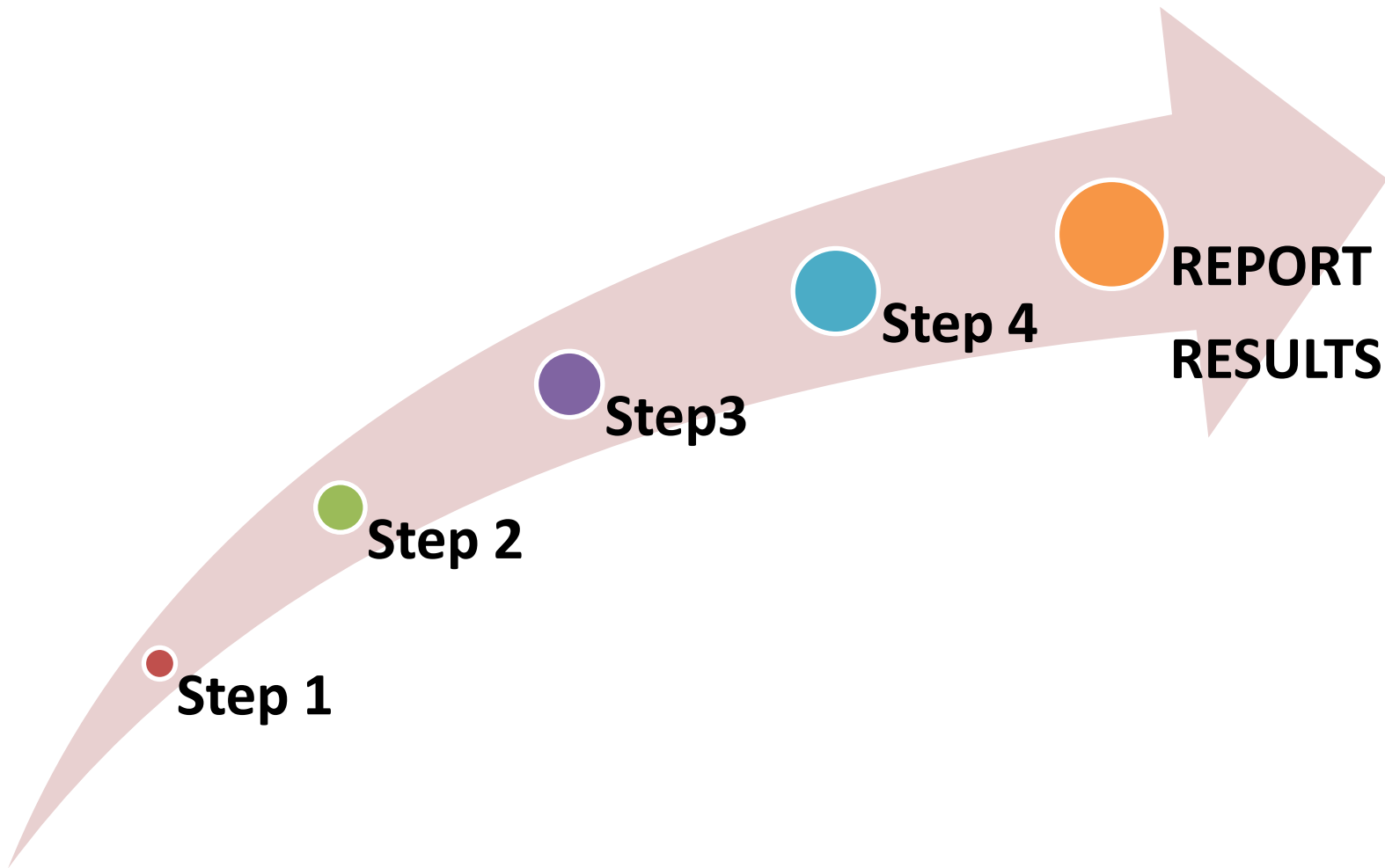
STEP 4

Does everything add up? Are there multiple assessments or changes in results?

EXAMPLE CHECKLIST

STEP	INCOMING CENTRAL UNIT DATA	BASE RECORD OR STUDY FORM DATA	MATCH AND MOVE TO NEXT STEP
1	Participant ID: 012345	Participant ID: 012345	
2	Date: 04/07/2012	Date: 04/07/2012	
3	10 observations	10 observations with corresponding entries	
4	1 assessment	1 study form	

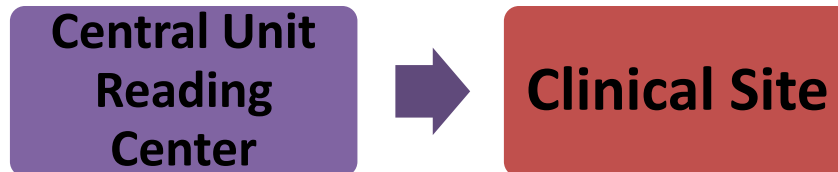
PASS CHECKLIST → REPORT RESULTS



STREAMLINE STEP BY STEP

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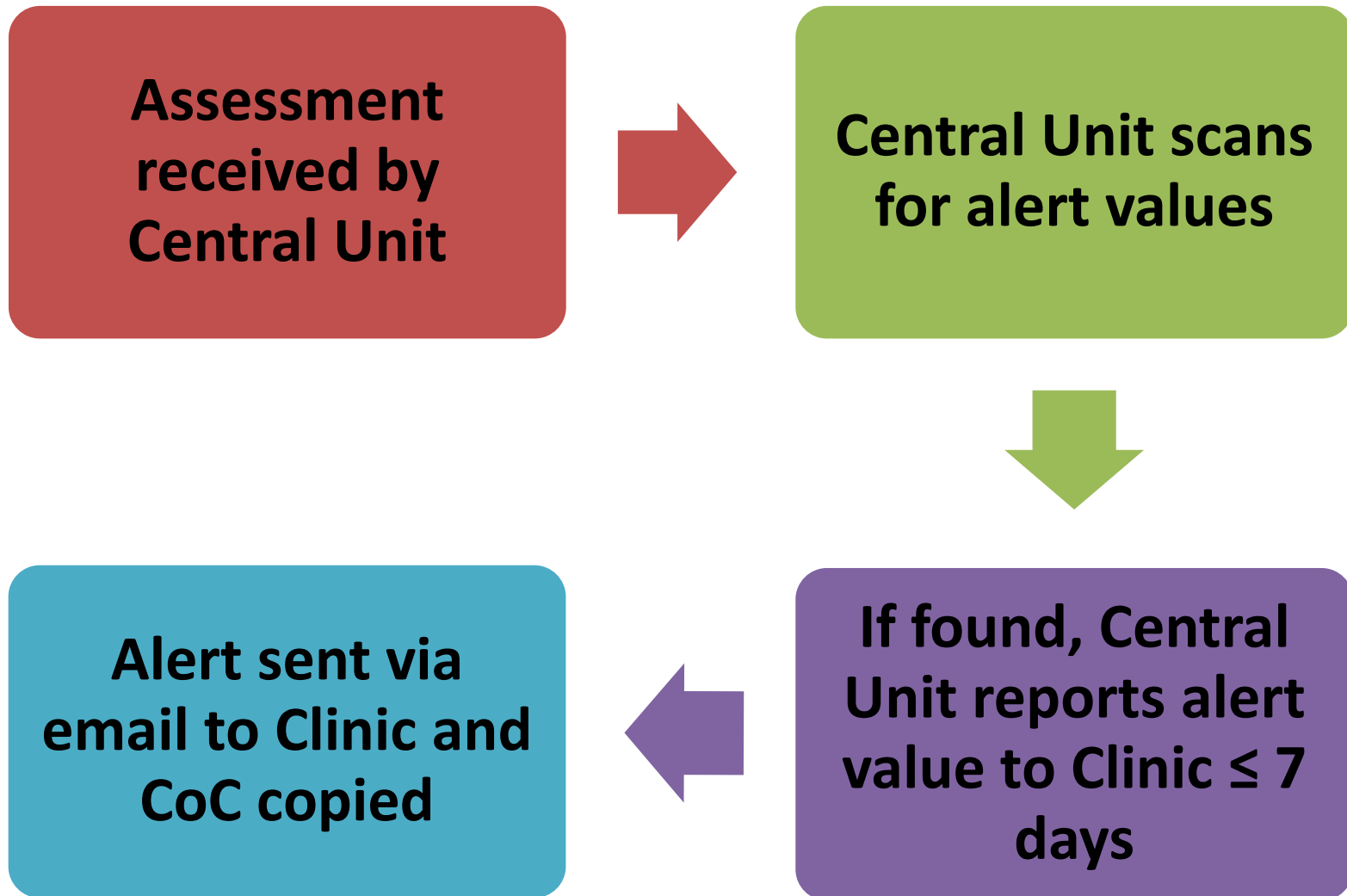
5. **Develop process reporting safety alert values from**



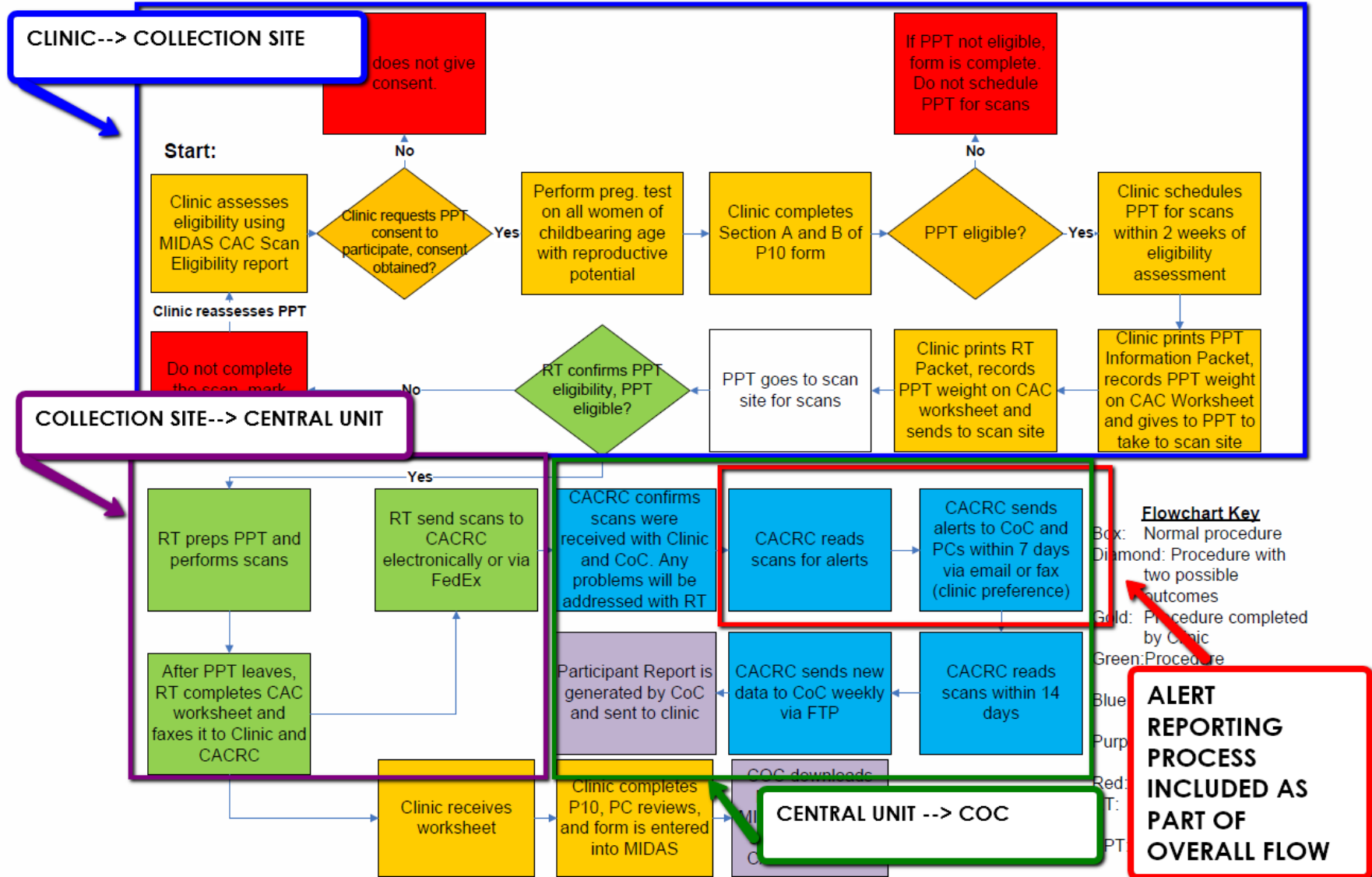
REPORTING SAFETY ALERT VALUES

- Request definition of alert values from Central Unit
 - Safety
 - Quality Control
- Create flow of safety alert reporting process with Central Unit
- Include flow in Manual of Operations

FLOW FOR REPORTING SAFETY ALERT VALUES



HELPFUL TO INCLUDE AS PART OF OVERALL FLOW





SUGGESTIONS

26

WOULD BE NICE...

- If possible, web-based portal to have the ability to generate real time reports for CoC members to pull themselves
 - Number of assessments collected in real time
 - Which analyses are complete or incomplete
 - Number and type of safety alert values reported
- Communication between Central Unit, collection site and Clinic to occur on web based portal in an interactive communication section so all parties are aware of informational exchange

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THANK YOU

28