



Preparing for Study Closeout

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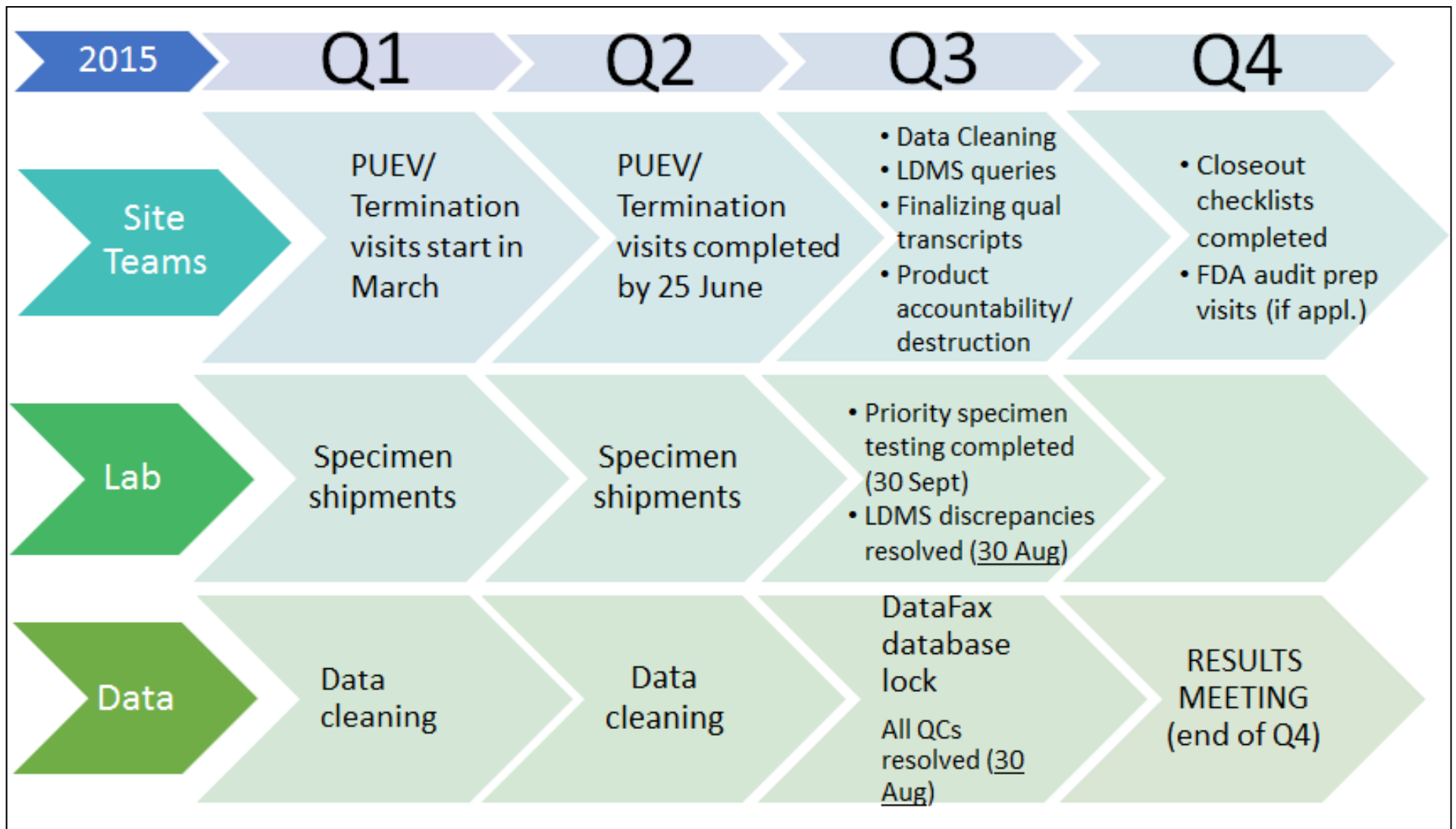
Cindy Jacobson, MTN Pharmacist

Overview of the rest of the afternoon

- Proposed closeout plan and timeline
- Data components of study closeout
- Pharmacy components
- Laboratory responsibilities
- Other operational responsibilities
- Community considerations (ASPIRE CWG)
- Contraceptive considerations (Zimbabwe CTU)
- Close out Q&A

Proposed Closeout Plan

- **PUEV:** From March – May 2015, participants will have their PUEV as they come in for their quarterly visits (PUEV conducted instead of quarterly)
- **Term visits:** 4 wks post PUEV; last visit date 25 June 2015
- Outstanding retention in ASPIRE has meant few participants who are hard to track
- To be vetted by the DSMB



If there is an effectiveness result...

Q1 2016= ramping up/HOPE activation process

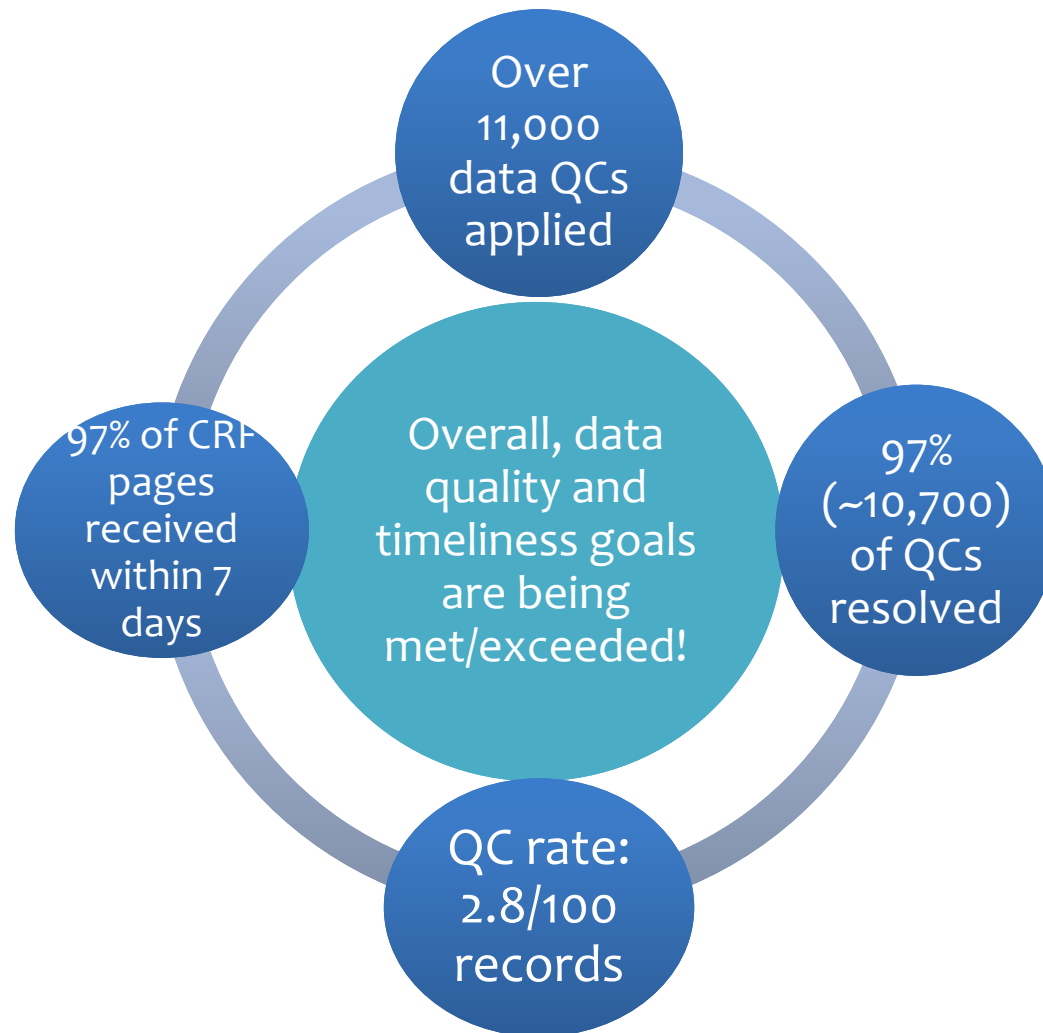
Q2 2016= implementation of HOPE

ASPIRE Data Quality Thus Far...

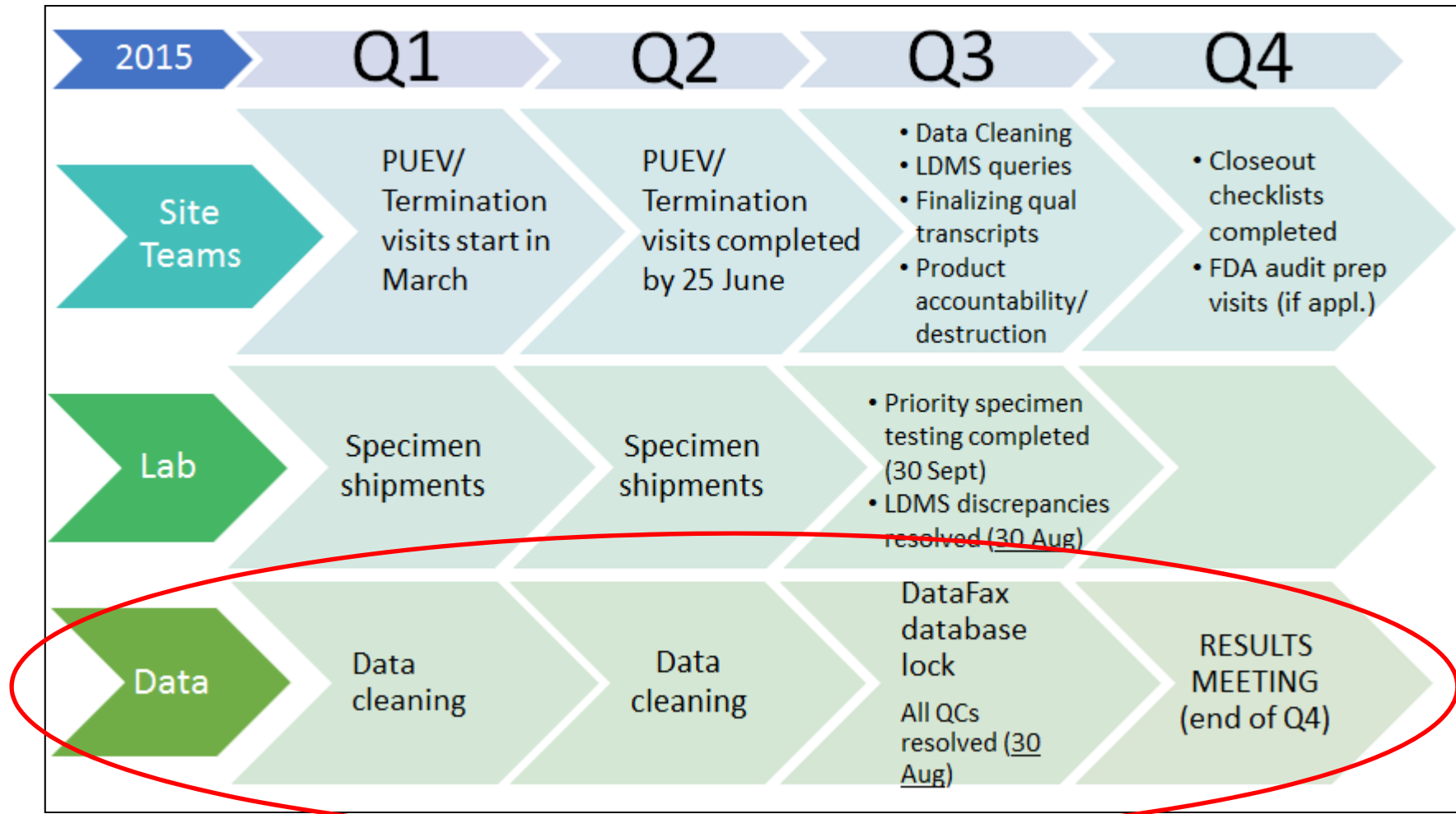
- ✓ Over 400,000 CRF pages received at SCHARP



ASPIRE Data Quality Thus Far...

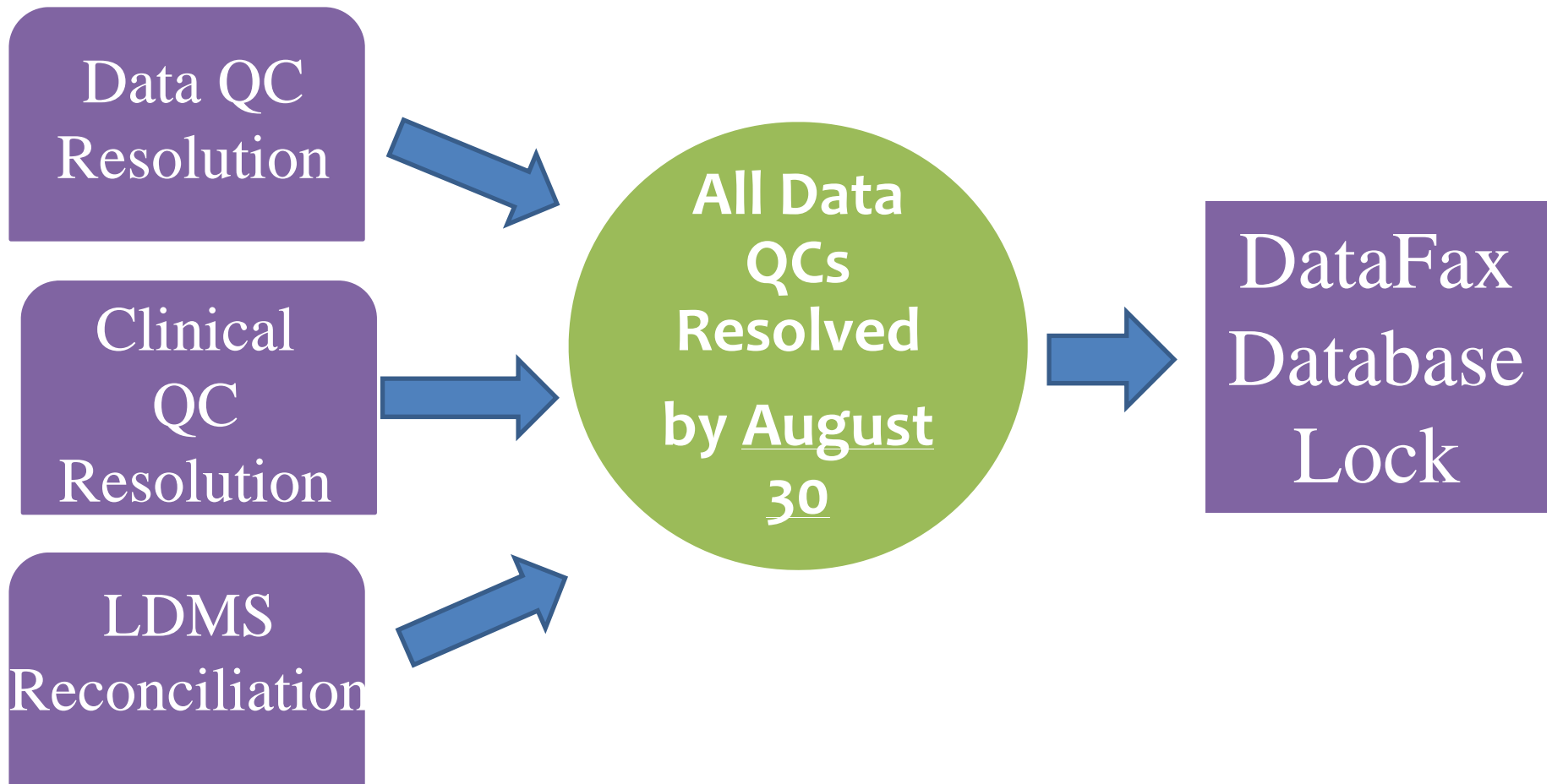


ASPIRE Study Closeout



ASPIRE Study Closeout - Data Cleaning

January - August, 2015



ASPIRE Study Closeout – QC Resolution

- We anticipate that, in total, sites will have approximately 500 data queries to resolve at the end of the study in June 2015 based on the QC Rate throughout the study.

ASPIRE Pharmacy Close-out

What will your site pharmacy do to prepare for study close-out?



Study Product Final Disposition

- Conduct final reconciliation of product accountability records
 1. Document final accounting of investigational products received at the site, dispensed to participants, and returned or destroyed.
 2. Review of all pharmacy participant specific files (prescriptions, request slips and other documentation in the ppt file).

Study Product Final Disposition

- Quarantine all remaining ASPIRE product and follow destruction as per pharmacy manual.
- Destruction process will not be initiated until the site pharmacist confirms (with me) that all documentation is in order.
- Study product destruction timing is outlined in the CTA and states the following:
 - ... upon completion of the Protocol, and the Clinical Research Sites shall provide written confirmation to IPM that such destruction has taken place **no later than fifteen (15) business days following IPM's request**

Process for Destruction

Kathie Windle
IPM



Dr. Lydia Soto-Torres
DAIDS

Cindy Jacobson
MTN

ASPIRE
Pharmacists

ASPIRE CLOSE-OUT

- **Review and assemble for long term storage and/or inspection:**
 1. All pharmacy source documents (including study product receipt, dispensing, accountability, and final disposition documentation).
 2. Resolve any outstanding monitoring findings and/or action items, and confirm with the appropriate monitor(s) that all have been resolved/completed.

Pharmacy Document Storage

- Pharmacy source documents must be kept in the pharmacy until the study has reached the DAIDS Enterprise System status of *Concluded*.
- Once this occurs, these documents should be archived in a folder or envelope marked as “pharmacy records” and stored together with other clinic documents.
- All pharmacy records should be retained for 2 years following the date a marketing application is approved for the drug for the indication being investigated: or, if the application is not approved, until 2 years after the investigation is discontinued.

Laboratory Closeout Activities

- Complete LDMS –CRF reconciliations (by August 30th)
- Complete LC directed specimen shipments
- Organize documents for potential audit

Operational Considerations (1)

- FHI 360 will be conducting closeout visits at each site from Jan-Nov 2015; Audit prep visits may also be conducted at some sites (Q4 2015/Q1 2016)
- The study closeout checklist will be distributed to sites in Q1 2015
 - Components related to final study visits, data cleaning, pharmacy, and lab
 - Ensuring all essential documents are complete, accurate and *organized*
 - Inventory taken of all study documents and locations
 - Monitoring visit findings addressed and documented
 - MTN Regulatory in receipt of all necessary staffing and regulatory documentation

Operational Considerations (2)

- Ensuring all qualitative files and essential documents are reviewed in parallel throughout this process
- Finalizing qualitative transcripts.
 - **GOAL:** All transcripts in to RTI by the end of July 2015; all finalized by end of August 2015

Operational Considerations (3)

- How will you maintain contact with participants to provide results/enroll in HOPE if applicable?
- Do you need to consider approaches now to seek prior IRB approval?

We'll hear more from the Blantyre and eThekwini teams on this tomorrow

Operational Considerations (4)

- Ramp down of 020, but there is still a lot of work to be done!
 - Staffing must be readily available to carry out all above-mentioned responsibilities as efficiently as possible
- Must be prepared for 025 ramp up in Q1 2016 if there is an effectiveness result

Summary

- Plan ahead!
- Rigorous, intentional implementation from activation through to the end.
- Be positioned for a rapid start up of HOPE
- We are almost there!!!

