

Study Closeout Expectations

ASPIRE Protocol Team Meeting

March 15, 2015

Statistical Center for
HIV/AIDS Research & Prevention

SCHARP

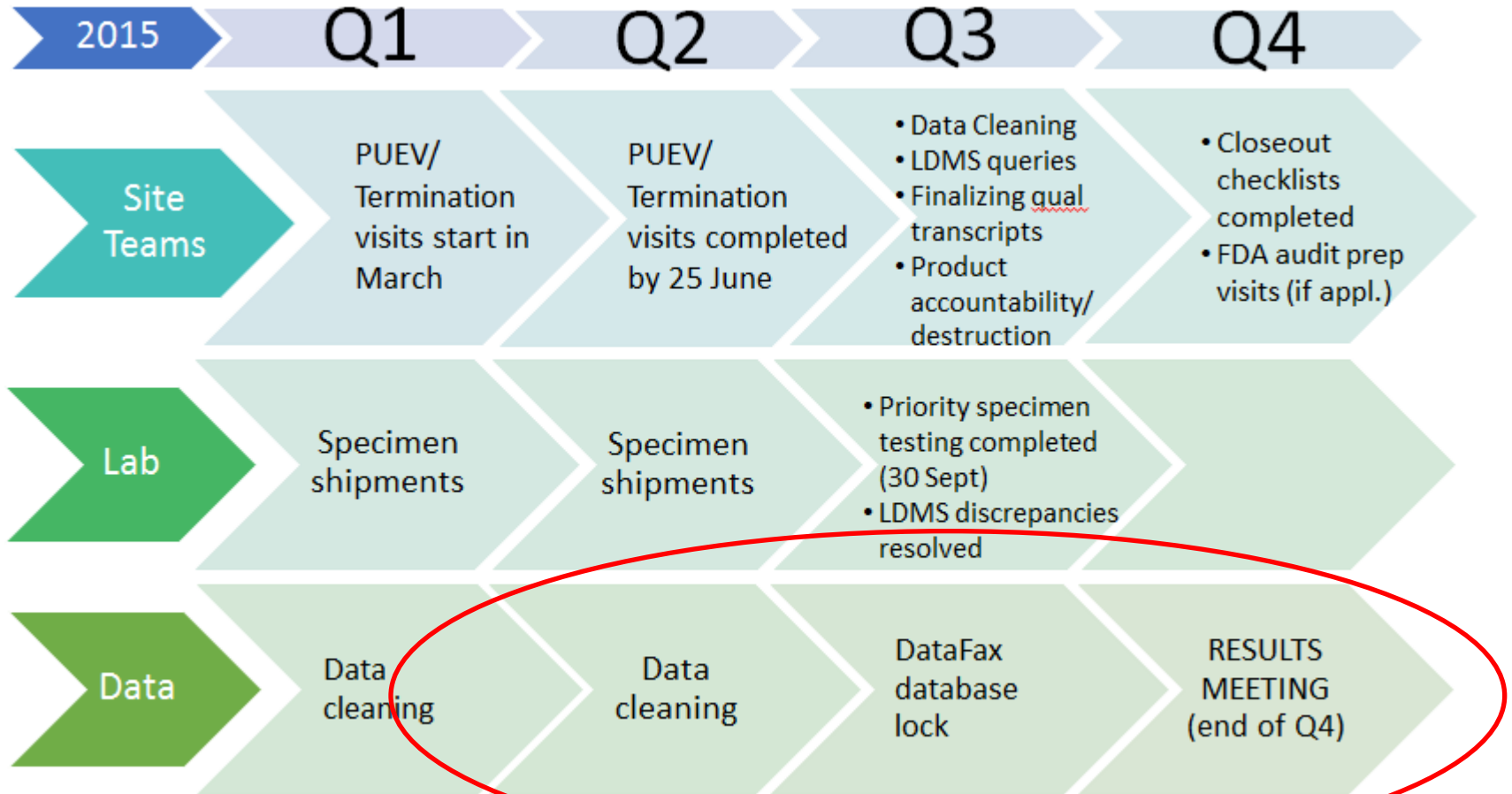
ASPIRE

A Study to Prevent Infection
with a Ring for Extended Use

Data Update

- Over **500,000** CRF pages received
- Over **14,000** QCs applied
- **97%** of QCs are resolved
- Cumulative QC Rate of **2.8 per 100 records**
- **95%** of CRF pages are received within 7 days
- Overall, data quality and timeliness goals continue to be excellent

ASPIRE Study Closeout



ASPIRE Study Closeout – What types of QCs can you expect?

- Data and clinical QCs (QC Report)
- LDMS Specimen Discrepancies (via email)
- IPM 027 data harmonization QCs (QC Report)
- Analysis QCs (QC Report)

To Note:

- ✓ These checks could potentially be on data received at SCHARP months,/years ago
- ✓ Additional checks may lead to a higher volume of QCs as we get closer to data lock. This is a reflection on the intensive data cleaning process and *not* on data quality on behalf of the sites.
- ✓ Important metrics are % of QCs resolved and # QCs remaining

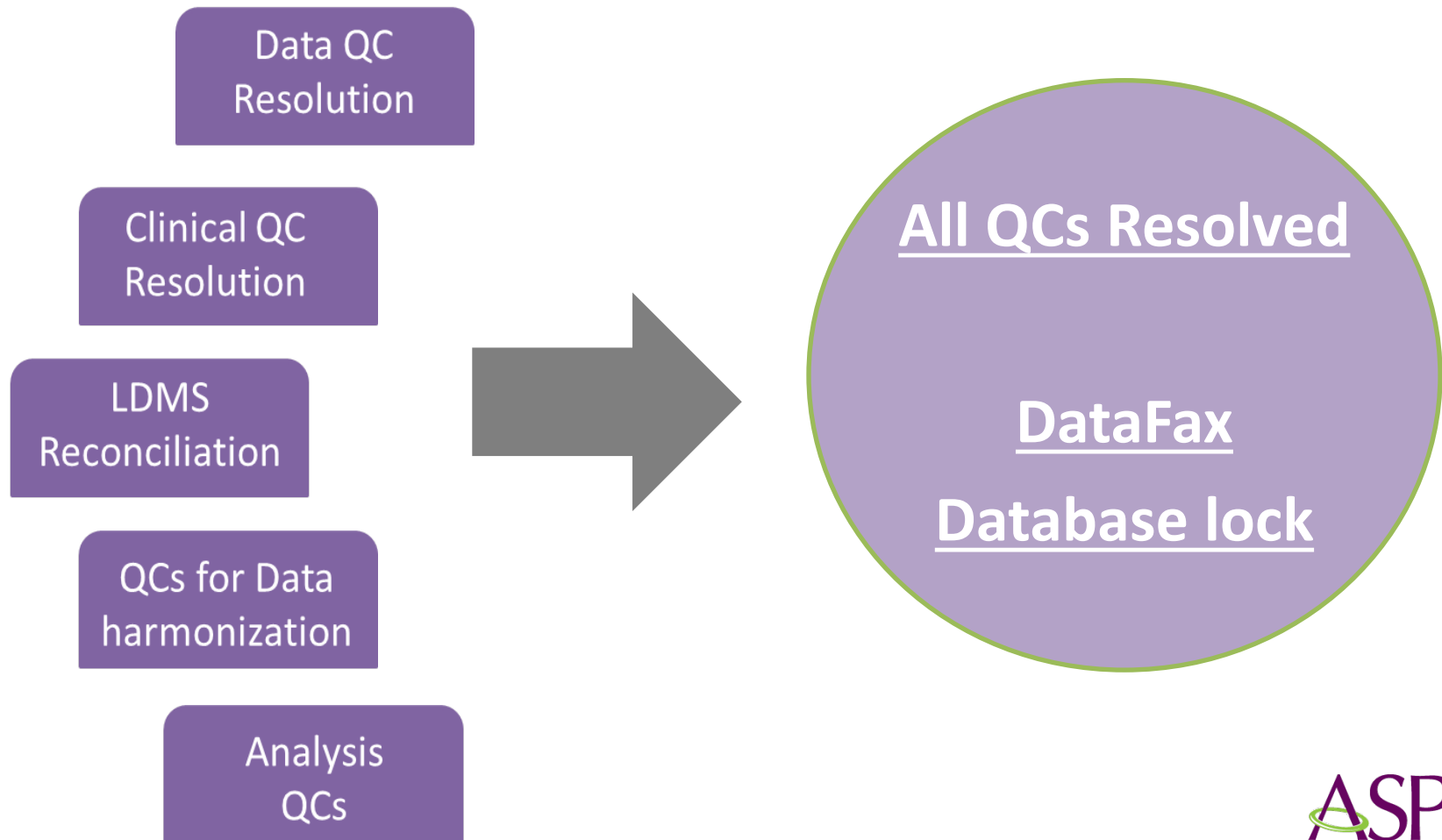
ASPIRE Study Closeout – Staff Considerations

- Ensure plan is in place so that adequate data/QC staff, time, and resources are available to address data issues and expedite resolution of additional volume of QCs even after last participant has completed follow-up.

ASPIRE Study Closeout – Common PUEV and SEV QCs

- SCHARP will provide guidance on those QCs that are the most prevalent across sites to help identify common form completion issues and clarify resolution for these QCs.
- Guidance will be available in in mid April.
- Please contact Jen Berthiaume, Jenn Schille, and Karen Patterson for any PUEV/SEV form completion questions.

ASPIRE Study Closeout - Data Cleaning



Questions?

