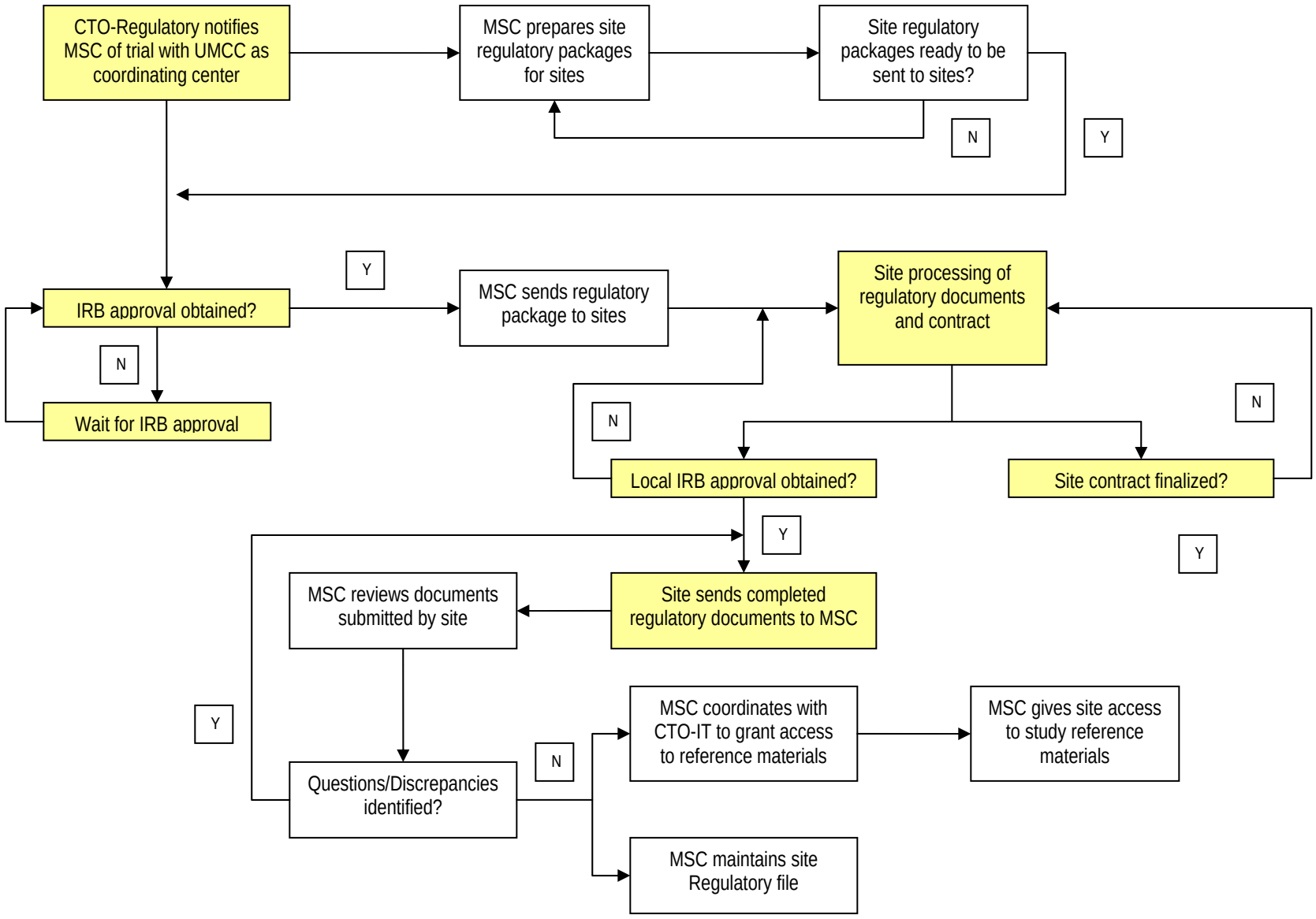
Multi-Site Coordination Process

MULTI-SITE COORDINATION (MSC) REGULATORY PROCESS



Regulatory Documents

From MSC to each participating site:

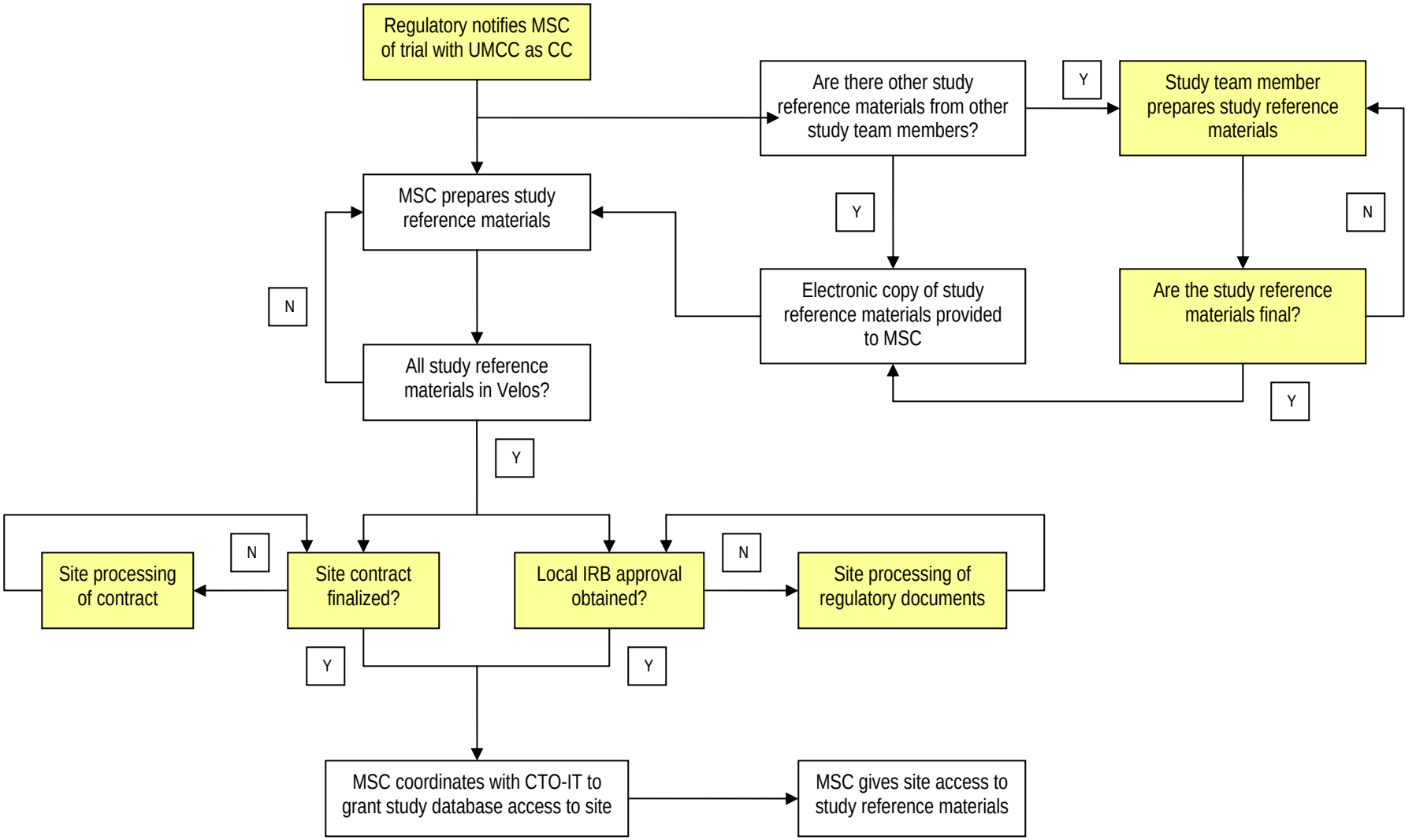
- □ Protocol and amendment, if applicable
- □ Model Informed Consent Form
- □ Protocol Acceptance Form
- □ IRB approval letter
- □ NCI approval letter, if applicable
- □ Investigational Brochure, if applicable
- □ Safety reports, if applicable
- □ Form 1572
- □ Financial Disclosure, if applicable
- □ Site contracts (to be provided by Finance, if applicable)
- □ Site Study Contact List

Regulatory Documents *(continued)*

From each participating site to MSC after local IRB approval has been obtained:

- □ Signed Protocol Acceptance Form
- □ Local IRB approval of protocol/amendment
- □ Local informed consent form and local IRB approval letter
- □ IRB roster of membership
- □ Form 1572
- □ Financial Disclosure of site primary investigator and co-investigator
- □ Current curriculum vitae of each study personnel
- □ Current medical licenses for primary investigator and co-investigator(s)
- □ Current CLIA Laboratory Certificate of Accreditation
- □ Current CAP Certification
- □ Current lab reference ranges
- □ Study contact list with contact information

MULTI-SITE COORDINATION (MSC) SITE PRE-INITIATION PROCESS

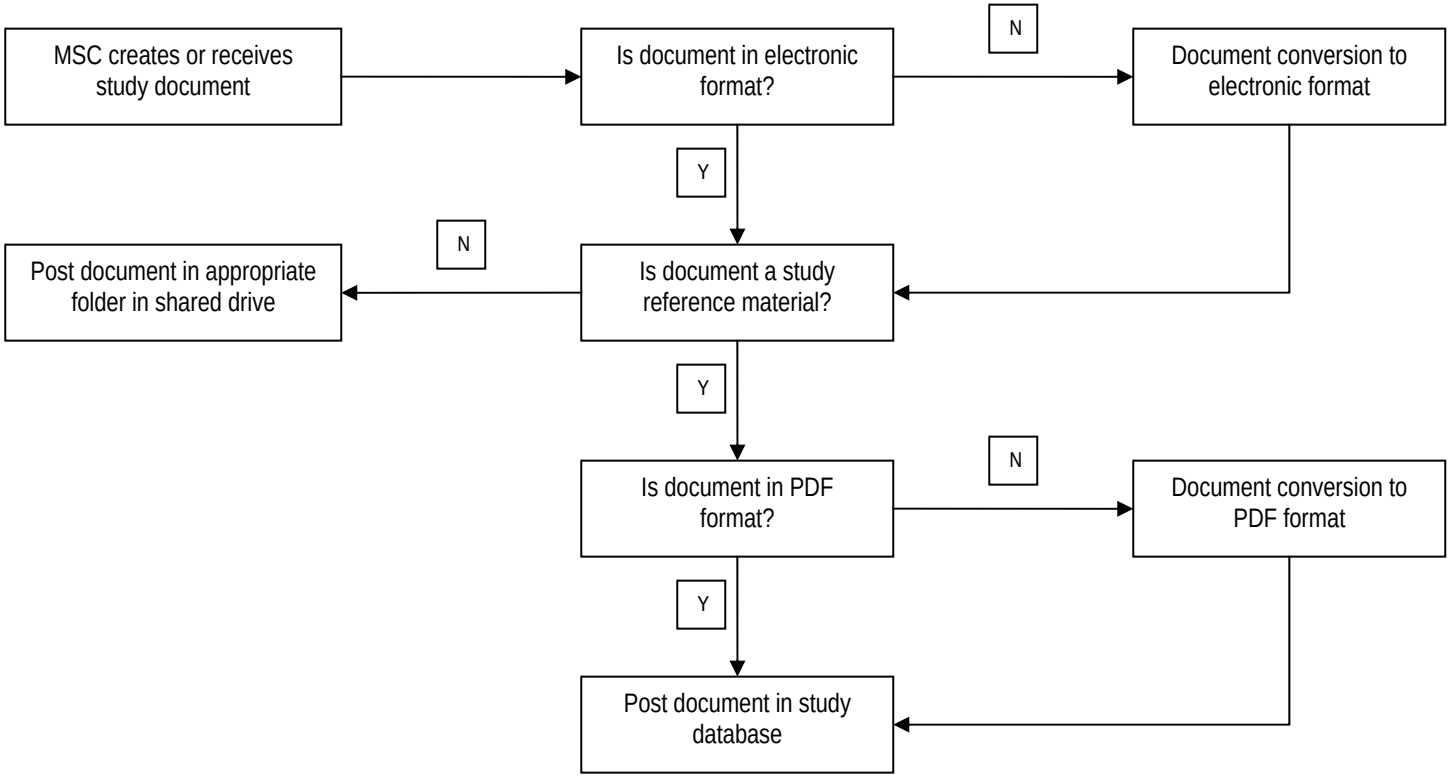


Study Reference Materials

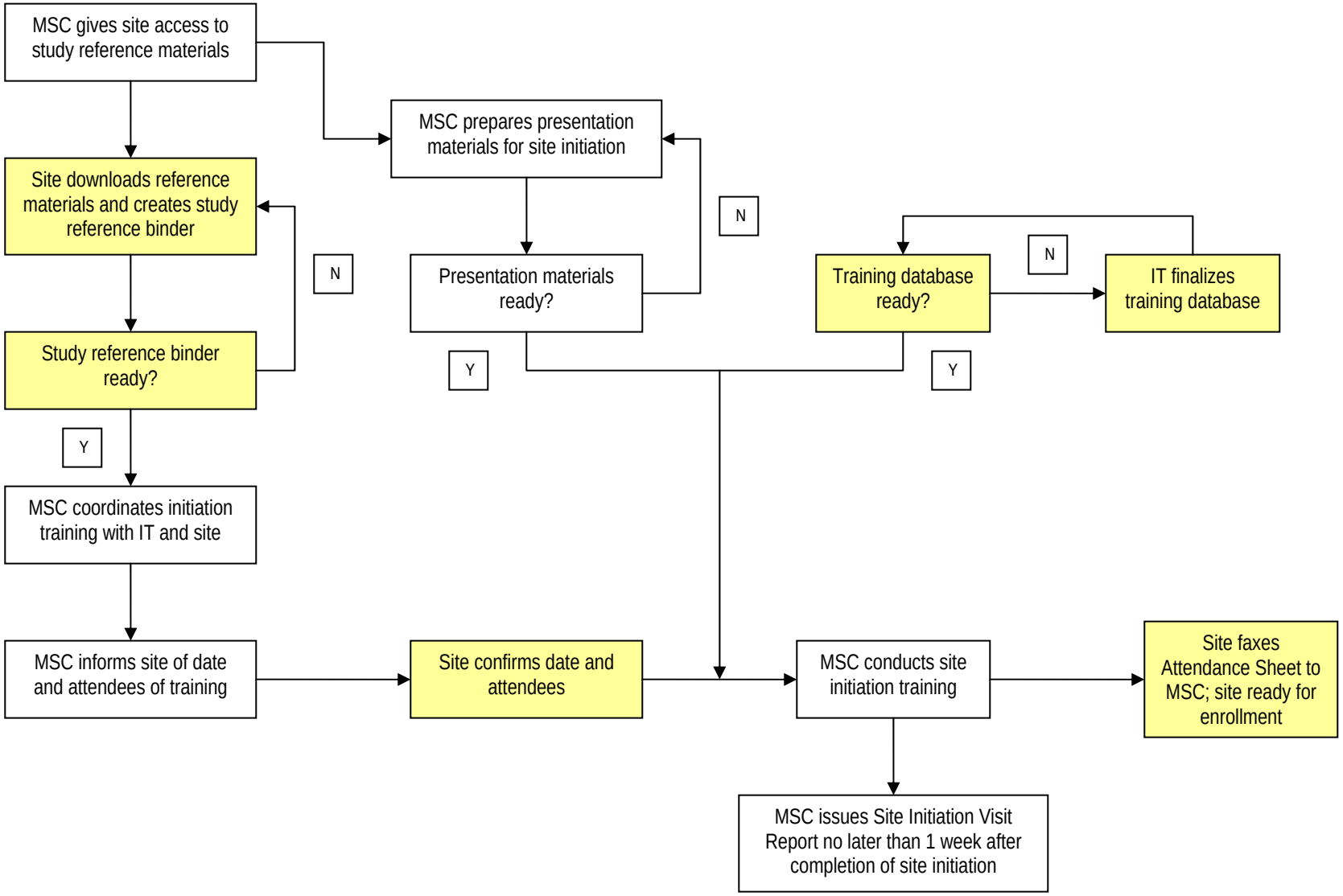
From MSC to each participating center:

- □ Binder cover and spine
- □ Table of Contents
- □ Contact Information
- □ Role of investigator, if applicable
- □ Protocol
- □ Study Enrollment Procedure
- □ Screening and Enrollment Log
- □ Delegation of Authority Sheets
- □ Monitoring Visit Log
- □ Correspondence
- □ Telephone Contact Report
- □ Velos Data Entry Overview
- □ Velos User Manual
- □ Patient Status Terminology
- □ AE/SAE Reporting Process
- □ CTEP AE Expedited Report, if applicable
- □ Drug Ordering and Accountability
- □ Pharmacy Dispensing Guidelines
- □ Data and Safety Monitoring Plan
- □ Data and Safety Monitoring Report
- □ Notice of Protocol Deviation
- □ Specimen Handling
- □ Shipping Instructions and Forms
- □ Specimen Labels
- □ Supply Order Form
- □ Lab Certifications
- □ Lab Normal Values

MULTI-SITE COORDINATION (MSC) STUDY DOCUMENTS FILING PROCESS



MULTI-SITE COORDINATION (MSC) SITE INITIATION PROCESS



Site Initiation Meeting Topics

Protocol

- ✓ Study design, requirements and compliance

Subject Recruitment

- ✓ Exclusion and inclusion criteria
- ✓ Enrollment process

Study Calendar

- ✓ Schedule of study procedures and assessments

CRFs

- ✓ Design and completion
- ✓ Data collection and database maintenance
- ✓ Data clarification process, if applicable

Source Data/Document Verification

- ✓ Guidelines

Drug Supplies

- ✓ Receipt, dispensing, return and accountability
- ✓ Storage requirements, as necessary

Site Initiation Meeting Topics *(continued)*

Laboratory Logistics

- ✓ Sample collection and shipment

AE/SAE Reporting

- ✓ Different required reports
- ✓ Processes and standards

GCPs and applicable regulatory requirements

- ✓ Data and Safety Monitoring process and requirements
- ✓ IRB re-approval needs and processes

Monitoring

- ✓ Frequency of visits and expectations
- ✓ Preparation for monitoring visits

Audits and auditing processes

- ✓ Preparation for a site audit

Records management and retention requirements

- ✓ Creation and maintenance of site master files

Site Initiation Meeting Topics *(continued)*

Issue resolution and communication process flow

- ✓ Review of site contact list and CTO-UMCC study directory

Unblinding Process

- ✓ Reasons
- ✓ Required documentation

Question and Answer

Throughout the entire site initiation, encourage study staff to raise any questions or feedback they might have. It is possible for a question/issue to be unanswered or unresolved by the end of the site initiation. In such a case, assure the site that those would be followed-up on until they have been answered or resolved.

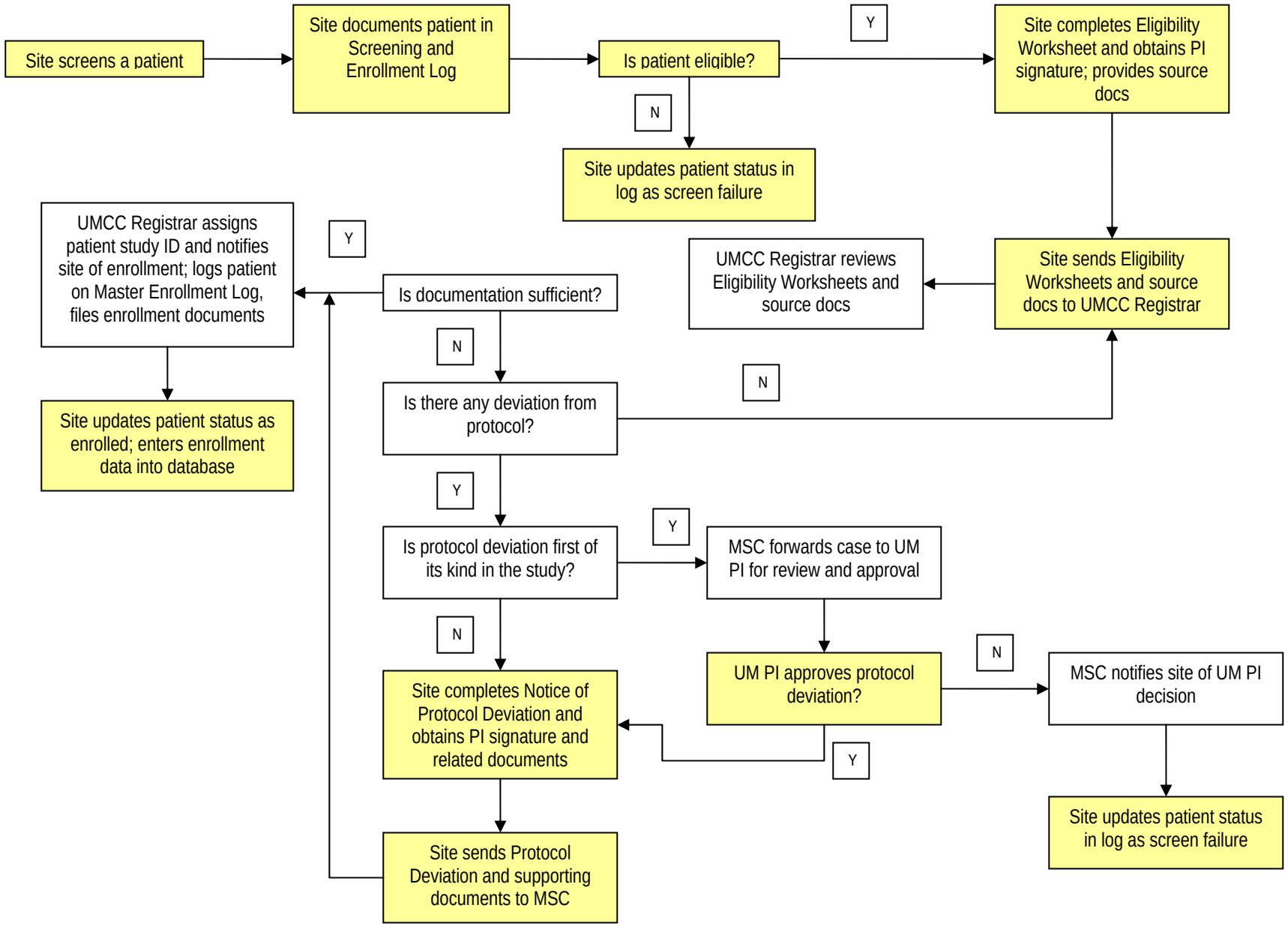
Site Initiation Participants

Recommended Site Participants:

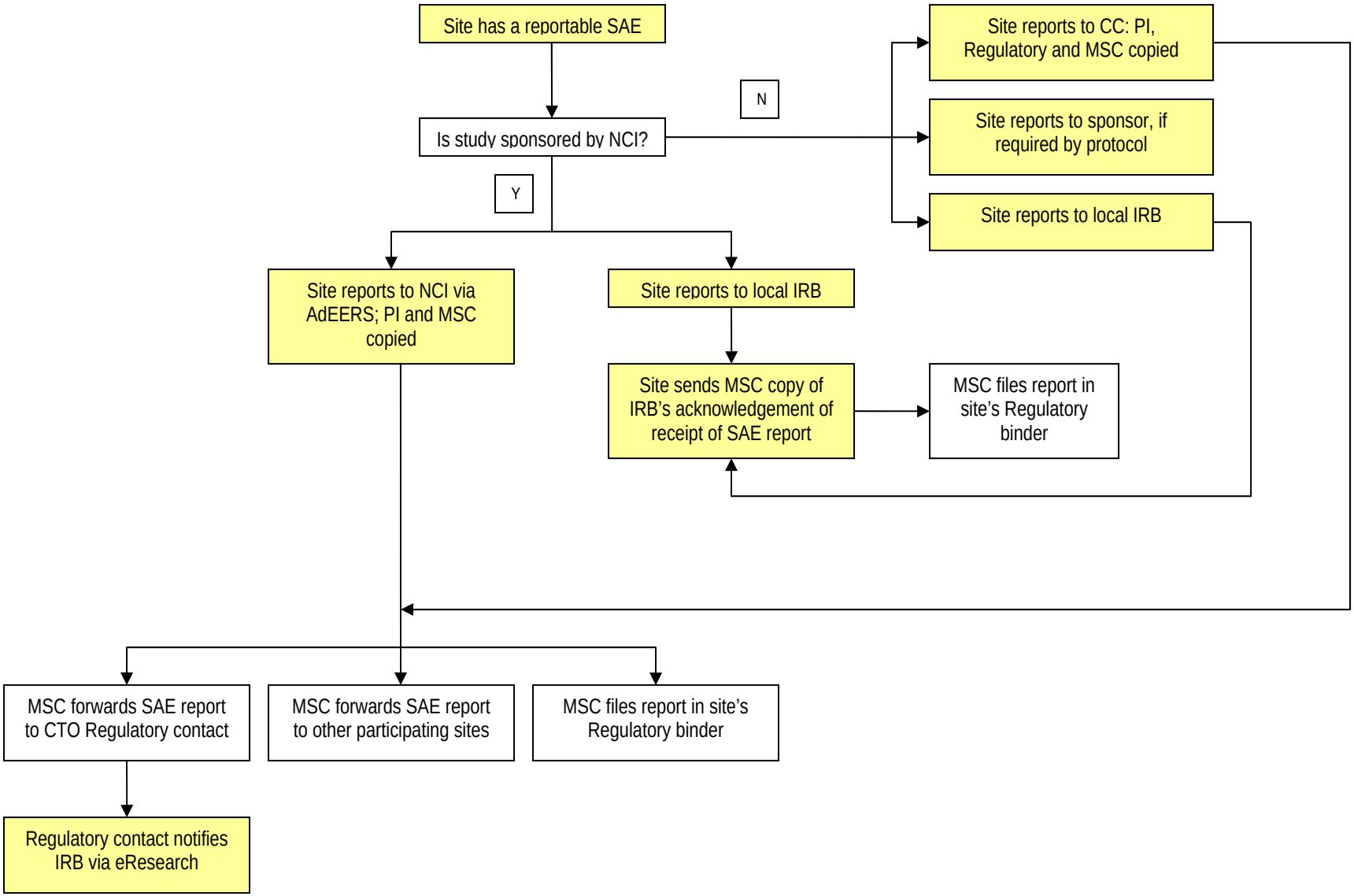
- ✓ Principal investigator
  - The principal investigator must make every effort to attend the site initiation. If not possible, the site's co-investigator should be in attendance.

- ✓ Site staff
  - Study coordinator
  - Study nurse
  - Pharmacist
  - All other study staff identified in the Delegation of Duties and Signature Log

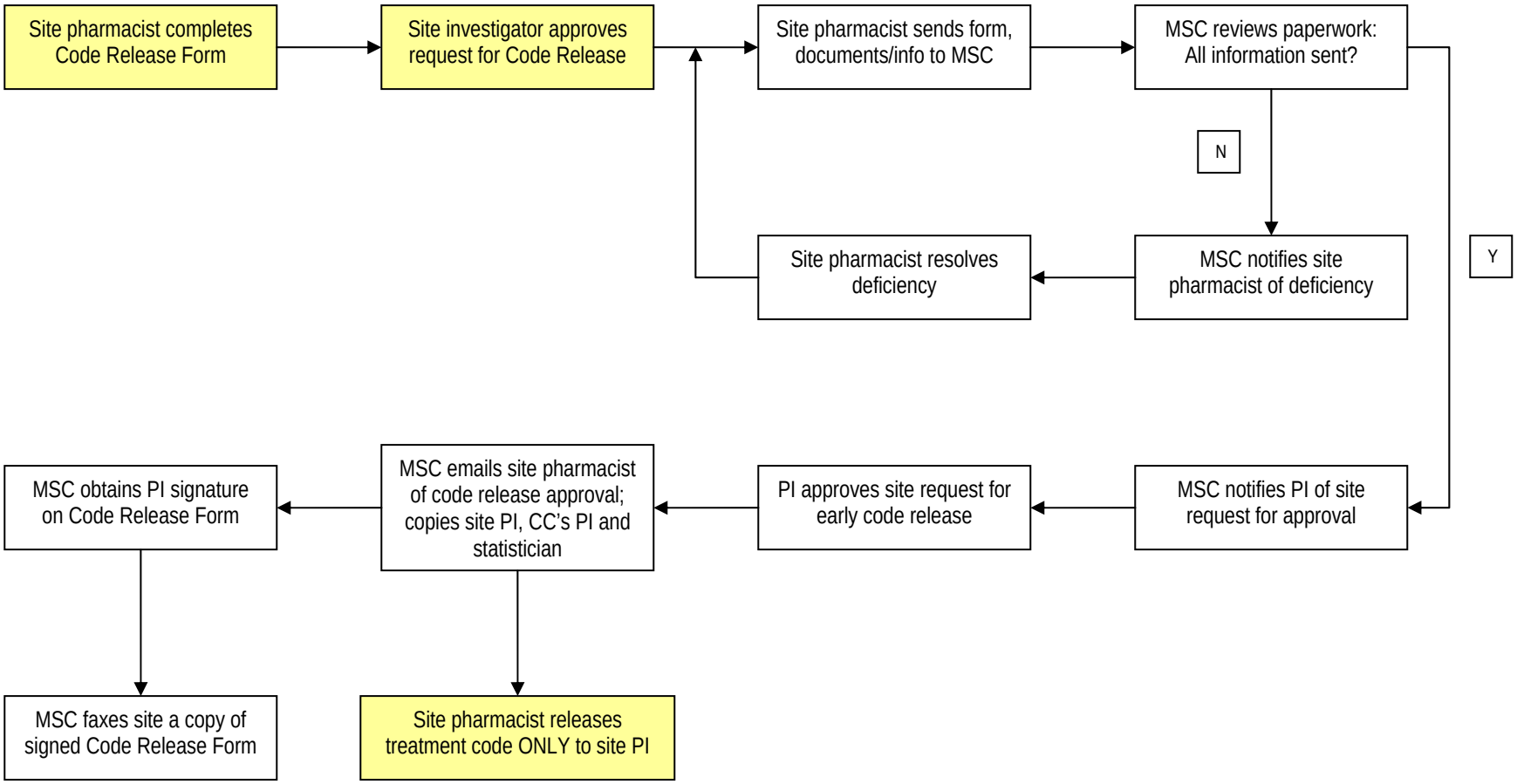
MULTI-SITE COORDINATION (MSC) ENROLLMENT PROCESS



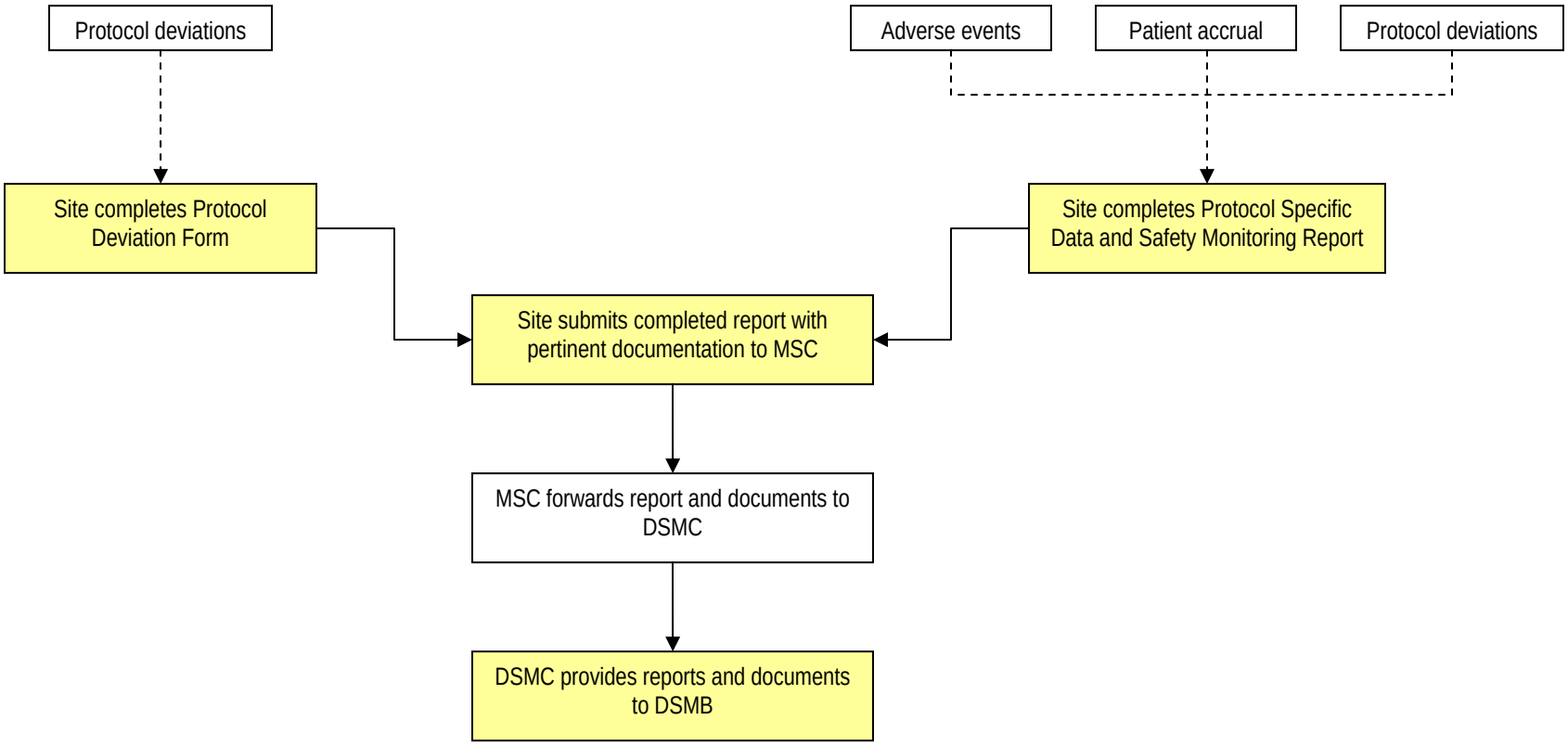
MULTI-SITE COORDINATION (MSC) SAE REPORTING PROCESS



MULTI-SITE COORDINATION (MSC) EARLY CODE RELEASE PROCESS



DATA AND SAFETY MONITORING PROCESS
(only for investigator-initiated multi-site trials with no independent external DSMB)



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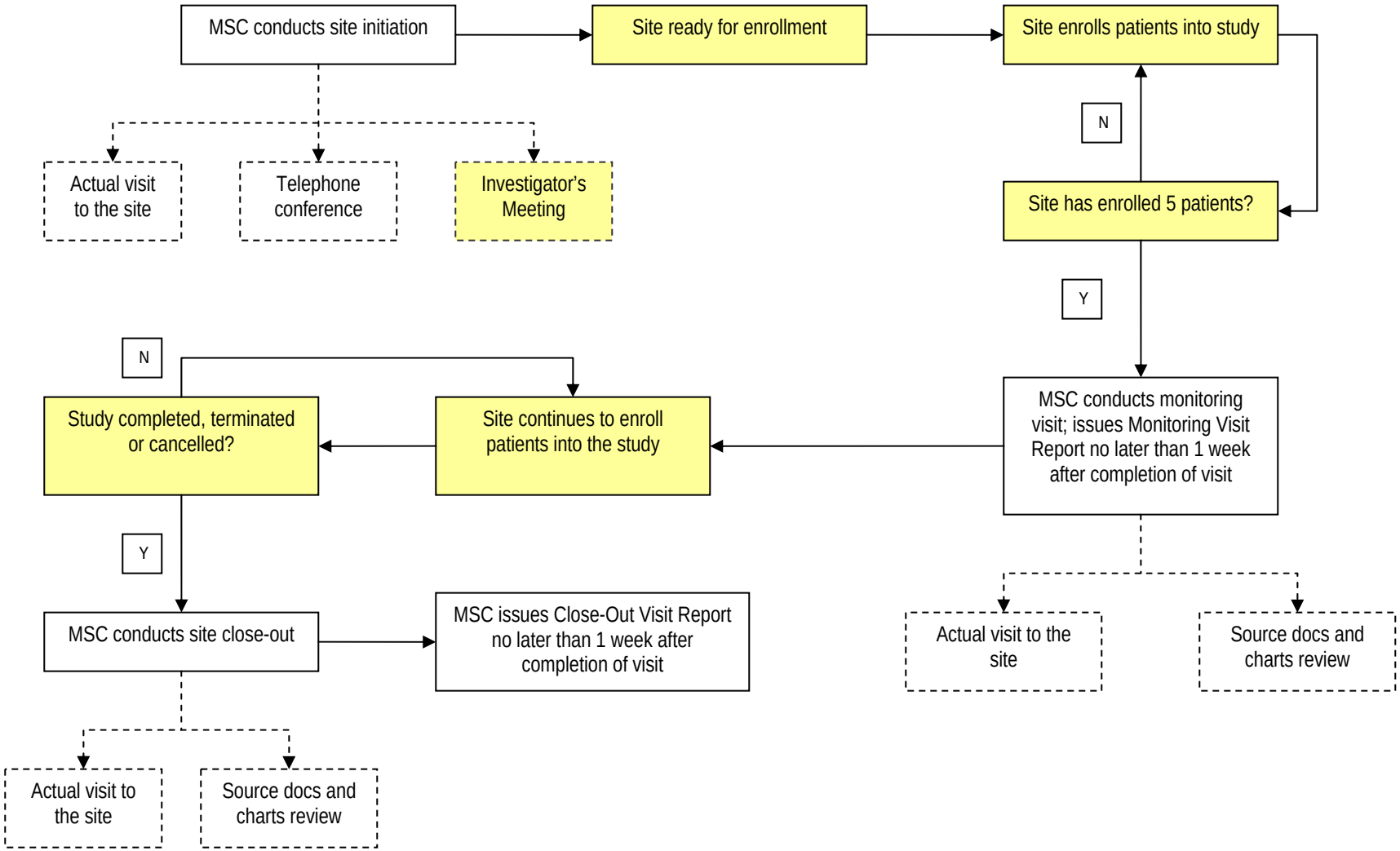
MULTI-SITE COORDINATION (MSC) MONITORING PROCESS



QUALITY ASSURANCE AND AUDIT