

Contract Concept: Quality Assessment Support

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Purpose of the contract

- Independent audits and inspections conducted of NTP testing facilities, study records, data, materials and reports
 - Findings communicated to NTP staff and management so they may be addressed
- Process aids the NTP in producing studies, data, and reports of the highest quality
 - The NTP has maintained a quality assessment support contract for nearly three decades
 - Present contract has conducted ~450 audits in the first 9.5 years of the current contract

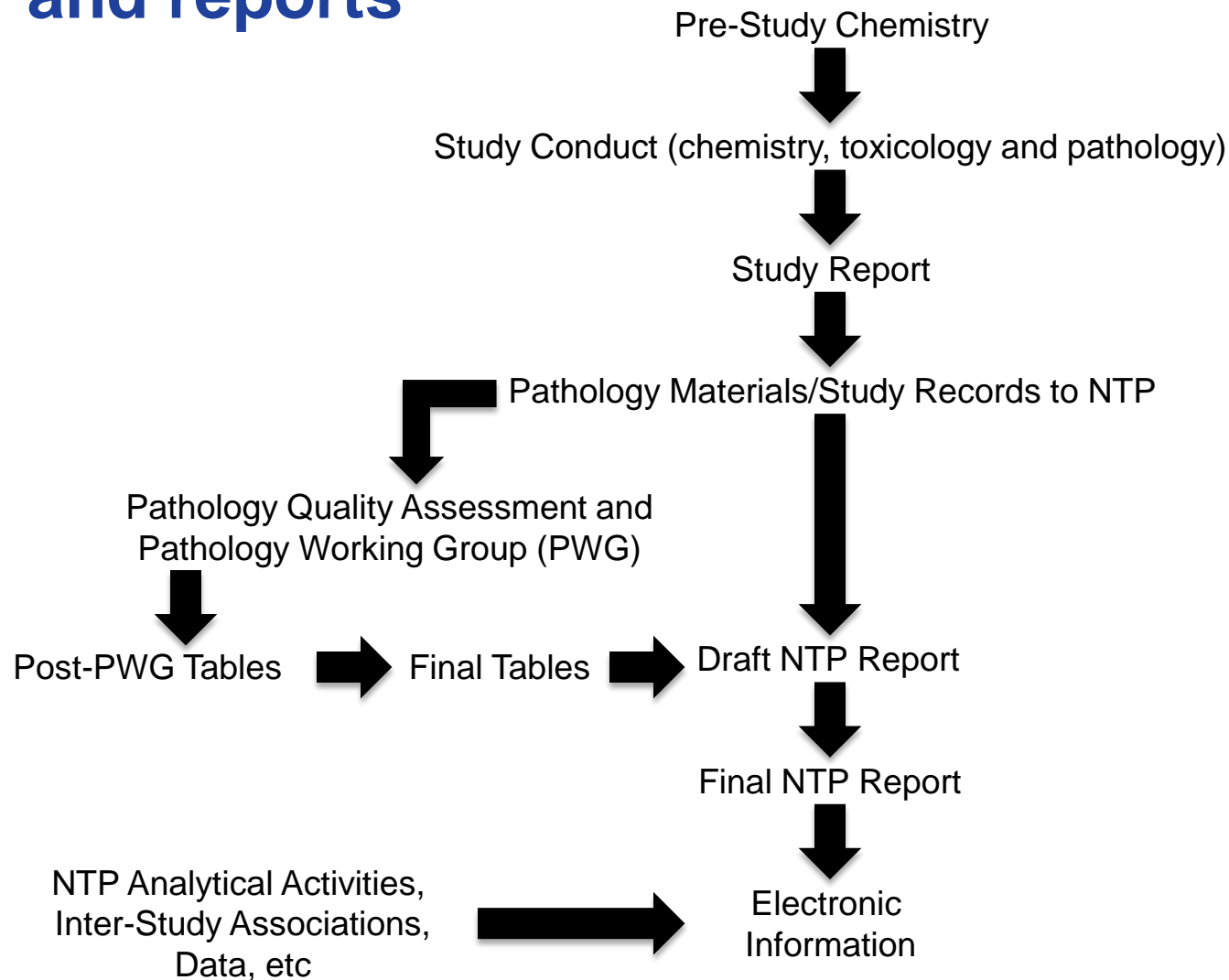
Types of audits and inspections

Type of audit/inspection	What is audited?	Audited against
Audit of Laboratory Report*	Final laboratory report	Study records and contractual standards (NTP specifications, GLP regulations)
Audit of Pathology tables	Post-PWG individual animal histopathology tables	Pathology Working Group (PWG) records
Audit of NTP Report*	Peer review draft report	Study records
Audit of Electronic Information	NTP website or database information	NTP website or database information or source documentation
Laboratory Inspection**	Procedures, facilities, equipment; data audits for studies in progress	NTP specifications and GLP regulations

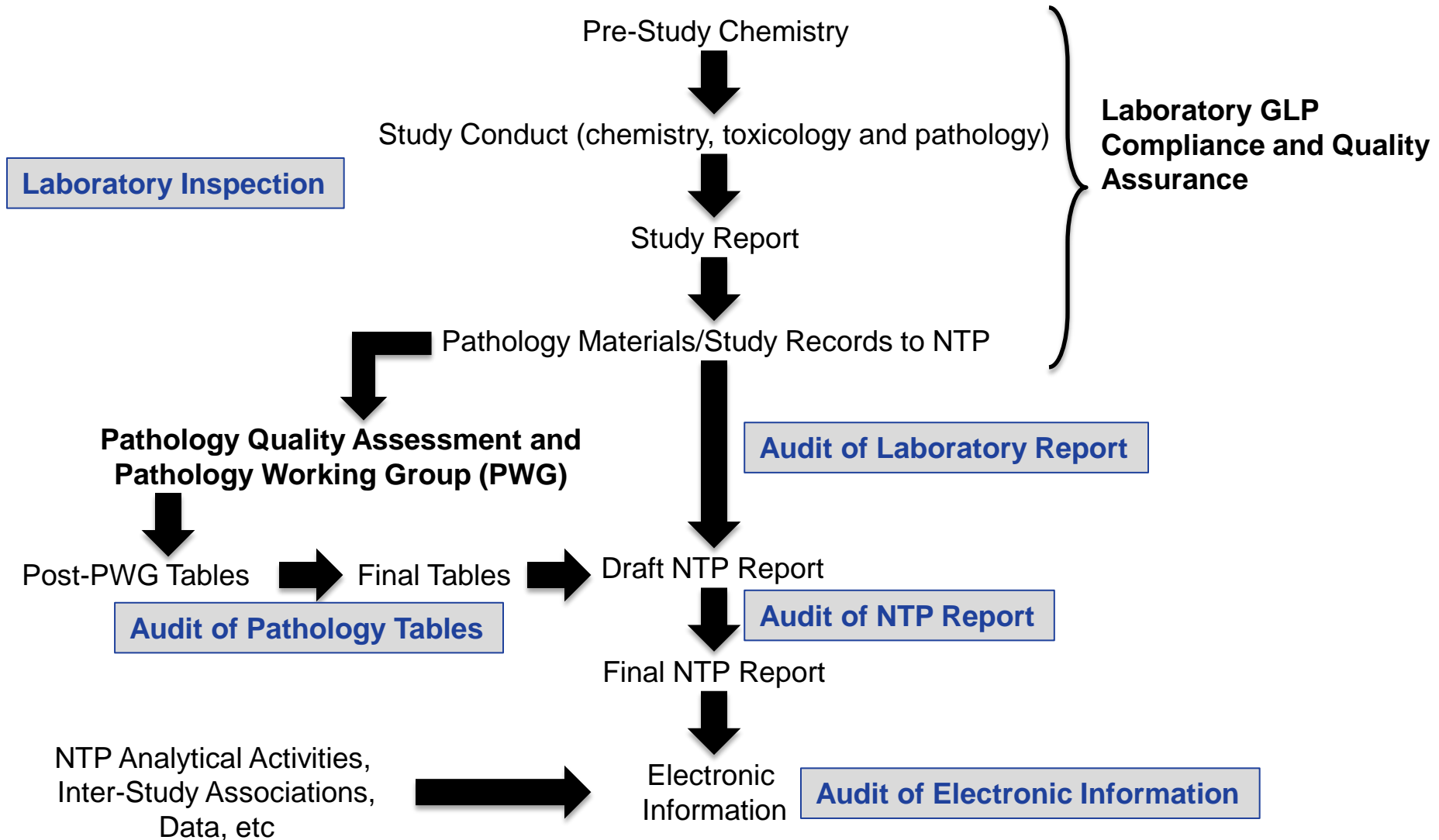
*Factual information (qualitative and quantitative) is audited for accuracy, consistency and completeness

**Quality Assessment Support Contract Staff accompany NTP staff on laboratory inspections

Conduct and reporting of NTP studies, data and reports



Quality of NTP studies, data and reports



Proposed changes to the current statement of work

- Changes to reflect the need for audit or inspection of NTP studies, data and reports of increasing size, complexity and diversity
- Capability to audit information and data used in NTP's literature-based evaluations and stored in electronic databases.

The BSC members are asked to review the concept for overall value and scientific relevance, as well as for fulfilling the program goal of protecting public health.

Specific areas for consideration:

1. scientific, technical, or program significance of the proposed activity
2. availability of the technology and other resources necessary to achieve required goals
3. extent to which there are identified, practical, scientific, or clinical uses for the anticipated results.
4. where pertinent, adequacy of the methodology to be used in performing the activity

The NTP seeks approval from the BSC to continue this type of activity using a contract mechanism.