

QUALITY ASSURANCE CLINICAL RESEARCH



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Quality Control and Assurance in Clinical Research

Quality: the total set of characteristics of a product or service that affect its ability to satisfy a customer's stated or implied needs. Quality system: the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

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Quality Assurance for Clinical Research CHLA

The Quality Assurance Plan (QA Plan) is designed to ensure that clinical studies conducted at Children's Hospital Los Angeles adhere to their respective research protocols, applicable federal and state regulations, the ICH-GCP guidelines and all relevant Children's Hospital Los Angeles policies and procedures.

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Quality Assurance

Other documents or specific sections of documents may be audited, although the practice of auditing every protocol, amendment and consent document is less common and considered to be a quality control activity performed within clinical research.

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Importance of Quality Assurance in Clinical Research Industry

Quality Assurance is the organized and independent assessment of all clinical trial-associated activities and records. The functions of the quality assurance department in the case of a particular clinical trial are very diverse.

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Quality Control and Assurance Applied Clinical Trials

Quality assurance (QA): the systematic and independent examination of all trial-related activities and documents. These audits determine whether the evaluated activities were appropriately conducted and that the data were generated, recorded, analyzed, and accurately reported according to protocol, standard operating procedures (SOPs), and good clinical practices (GCPs). 4

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QUALITY ASSURANCE IN CLINICAL RESEARCH

QUALITY ASSURANCE IN CLINICAL RESEARCH Adam Weerdenburg Research Quality Assurance Officer & Financial Assistant Research Administration Charlton Campus, Martha Wing H307

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Quality Assurance in Clinical Trials An Introduction to GCP

One part of Quality Assurance in Clinical Trials is adhering to Good Clinical Practice (GCP). GCP is defined by EU Directive 2001/20/EC, article 1, clause 2 as: GCP is defined by EU Directive 2001/20/EC, article 1, clause 2 as:

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