ICH E8(R1) Final Version

GENERAL CONSIDERATIONS FOR

Adopted on 6 October 2021





PROTECT

PATIENTS

Determine

the risks

threatening their

integrity

KEY ASPECTS OF A QUALITY APPROACH TO STUDY DESIGN

The objectives

can be met by the

chosen design and

data sources

Study

hypotheses are

specific, timely

and scientifically

valid

Protocols and

case report forms/

data collection methods

enable the study to be

conducted as

designed

RISK TO QUALITY

Identify clear

critical to quality

factors when

designing a

study

Clearly

articulated

objectives of the

study

These needs are

meaningful to

patients

FOCUS ON CRITICAL TO QUALITY FACTORS TO:

GENERATE RELIABLE &

MEANINGFUL

DATA

Implement

control

process to

manage risks

Study is

designed to meet

the need it sets

out to address

Study

design is

operationally

feasible

GOOD DESIGN



Clear objectives and endpoints that address the primary scientific questions; selection of appropriate subjects & sites; approaches that minimize bias.

(randomization, blinding or masking, control of confounding)

Ensuring feasibility quality of

GOOD DESIGN EXECUTION

facilities everywhere, procedures & processes.

Overreliance on retrospective documents checking, monitoring, auditing, inspections.

CONSIDERATIONS IN IDENTIFYING CRITICAL TO QUALITY FACTORS



Determine the probability and impact of those risks

Engagement of all relevant stakeholders during study planning

> Study design supports a meaningful comparison with the chosen control group

Number of subjects, duration of study & frequency of visits are sufficient to support the study objective

Choice of response variables and assessment methods support the drug effect evaluation

Systems and processes are in place to ensure the integrity of critical study data

clinical studies are complete and adequate to support the study being designed

Non-clinical and

Adequate measures are used to protect subjects (informed consent, IRB/IEC review, pseudonymisation, etc.)

Eligibility criteria reflect study objectives and are well documented in the protocol

Procedures include adequate measures to minimize bias

Extent and nature of study monitoring are tailored to specific study design & objectives

Study objectives address relevant scientific questions

Feasibility assessment confirmed the study operational viability

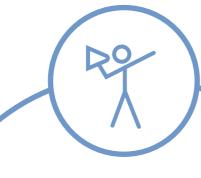
Information about subjects important to understanding risk/benefit is specified in protocol, design, conduct & analysis

SAP is pre-specified and defines the analysis methods appropriate for the endpoints and populations

> Need for a data monitoring committee is assessed



QUALITY CULTURE



Encourage proactive open dialogue



Discourage "one size fits all" approach



Engage broad range of stakeholders (including external ones)



Train stakeholders prior to the first subject enrolment and during the study



Go beyond the reliance on tools and checklists



Choose quality measures and performance indicators that are aligned with a proactive approach to design



Build on experience and knowledge



Periodically review critical to quality factors to determine whether adjustments to risk control are needed



Use innovative methods for ensuring quality