# Review Process (Peer, Technical and Data)


Module 11 Topic 9

- Peer review refers to the evaluation of a document by peers of authors, i.e. typically doctors and/or scientists belonging in the same area of specialisation or subspecialisation
- Peer reviewers aim to provide a critical, independent and unbiased assessment of the scientific document, and are regarded as an important extension of the scientific process
- Peer review aids in gatekeeping of what goes into the knowledge pool, and has been adopted by all major medical and scientific journals

- The reviewer should be an expert in his field and is required to render an unbiased opinion on the quality, timeliness and relevance of the document
- The reviewer has a responsibility to the author in treating each document with respect, fairness and impartiality
- He should always bear in mind that the submitted document is an intellectual property belonging to the author, and should be regarded as a highly privileged piece of communication

- The reviewer should refrain from publicly discussing the contents of the document, and must not make use of knowledge of the author's work to further his own interests or for private gain
- It is recommended that the reviewer should not keep any copy of the document after completion of the review

# Variations in the peer review process

- Online versus hardcopy review
- Open versus single- or double-blinded review
- Recommendation or blacklisting of reviewers by authors
- Financial and other incentives for reviewers
- Quality control of reviewers
- Feedback process to reviewers regarding editorial decisions
- Education and training of reviewers

# Pros

- Research work is validated through experts
- Improvement in the quality of publications – through constructive feedback mechanism
- Publication of most important research in journals – enables journal editors to select articles based upon the objective and independent reviews of an expert group
- Peer review process is well understood and accepted by majority of researchers

# Cons

- Time consuming process – may cause delays in the dissemination of research findings
- Effectiveness of the peer review process is debatable in detecting errors in academic papers
- Anonymity of referees is difficult in specialized research fields – very few experts available

# Cons (contd)

- Publication of poor research may not be prevented – review standards may be lower in less prestigious journals
- Reviewer's bias:
  - Conflict of Interest: Reviewers may support the findings of their own interest and oppose publication of competing ideas
  - Attitude: Unconventional ideas are not easily accepted; force editors to add their own references
  - Status: Influence of reputed institutions and scientists on reviewer's recommendations

# Cons (contd)

- Unable to uncover scientific misconduct: plagiarism, duplicate publication, fabrication of results, falsification or adjustment of data, violation of ethical standards
- Delay in the publication process: deliberate delay in decision making
- Unable to detect major flaws: examples include –
  - Fraud at the bell laboratory (1998-2002)
  - Fraud in stem cell research conducted by Korean researcher in 2005 was detected when retested by other scientists
  - Inadequacy to detect weakness in the manuscript
    - A study showed that surprisingly only 2 mistakes were detected by the 200 reviewers in a manuscript with 8 deliberated weaknesses

# Quality control-A Type of review

# The Why, What, When & Who of Quality Control (QC) of Medical Writing Deliverables

- Quality control (QC) is a term that applies across many industries. Within the field of regulatory medical writing, QC refers to the process of ensuring the quality and accuracy of a final medical writing deliverable.

# Why QC?

- To deliver a document of the highest quality
- It's required by the guidance set forth by the International Council for Harmonisation (ICH):
  - "The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled."

ICH E6: Guideline for Good Clinical Practice

# What is QC?

- The primary purpose of QC is to verify accuracy of 100% of the data presented in the document
- A QC of any document should include:
  - 100% data QC (all data verified against a source);
  - Confirming that non-numeric information presented reflects the source (eg, protocol, statistical analysis plan);
  - Ensuring consistency of appearance and adherence to an agreed-upon style guide (whether from the Sponsor or IMPACT);
  - Checking for consistency of presentation, format, grammar, use of abbreviations (and the list of abbreviations, if present), references cited; and
  - Confirming cross-references in the document are correct

# Who is Qualified to Perform QC Activities?

- The most important part of the “who” question is actually who should **NOT** QC
- The QC should never be performed by the author and should not be performed without appropriate training
- **Why not the author?** The document deserves a fresh eye. Data errors, grammatical mistakes, and formatting are often missed when an author has had the document in front of him/her for days or weeks
- Any medical writer with keen eye for details and is qualified/ trained for this task

# Points to consider as a reviewer

**Stick to the facts**

When you write questions or comments, try to keep your language neutral, focusing on how you think the language should change. Starting a comment with a “why are we saying” or “shouldn't this be” adds an accusatory tone that doesn't help solve the problem at hand

# Points to consider as a reviewer

**Seek consensus for complicated issues**

Sequential review is a time saver only when everyone understands the issues to be resolved. If you'd like to request a change that is too involved to mention in written format, it's best to visit or call any necessary stakeholders, if time and schedules allow, to gain agreement on a solution. Similarly, if you see someone has raised a complex question, try to talk offline to resolve it, rather than add more running dialogue to the job

# Points to consider as a reviewer

**Explain your reason for wanting a change**

To clear the air that changes you request are necessary and are not the subjective comments of a slash-and-burn reviewer, add a few words to explain your rationale. For example, “For clarity, I suggest changing to...”

# Points to consider as a reviewer

**Communicate clearly**

Only use abbreviations and unique terminology if you know the other reviewers will understand them. In word, use track changes and review comments efficiently to mark up exact changes required. If you are marking in a format like a PDF, utilize the mark-up and commenting tools in a way that makes it clear as to which block of text you are discussing

# Points to consider as a reviewer

**Review your comments before sending the job along**

Look over your comments before sharing the document, just to make sure they make sense. You can also use this time to delete comments that you have resolved yourself during the course of your review. Additionally, a final check will allow you to make sure you have not forgotten any key information or neglected to raise any additional questions that are on your mind