abpi
Bringing medicines to *life*

Disclosure/transparency checklist:

Self-training and Q&A materials

abpi
Bringing medicines to life

Disclosure/transparency checklist:

Self-training materials

abpi
Bringing medicines to life

How to use the checklists

- **Make yourself familiar with the underlying <company name> processes and procedures (eg policies, SOPs, manuals).**

- **Remember that any checklist does not reflect all possible aspects of a business process but is constructed to reflect general and standard scenarios.**

- **If you detect a missing element in the checklist, please inform the Disclosure Co-ordinator (the term Disclosure Co-ordinator designates in this context the individual who has overall accountability for disclosure matters).**

- **Respond to all questions in the questionnaire accurately and should you not be 100% sure about the answer obtain the information from the relevant subject matter expert rather than making an 'educated guess'.**

- **If the questionnaire reveals issues in the disclosure process or tasks, address these issues in a timely manner.**

How to use the checklists

- **File completed questionnaires as per <company> records management and archiving policies as they represent an important evidence of the quality measures adopted to ensure compliance of <company> with legal, regulatory or industry rules and best practices, respectively.**

abpi
Bringing medicines to life

Disclosure/transparency checklist:

Question and answers

Disclosure process checklist

abpi
Bringing medicines to life

- **When should the questionnaire be completed?**
  Answer: It is recommended to complete it when the disclosure process is set up, changed or, if a process is already in place, as part of the quality oversight activities.

- **Who should complete the questionnaire?**
  Answer: It is recommended that the person responsible for the disclosure process completes the checklist or as a minimum oversees its completion and ensures that issues noted get addressed in a timely manner.

- **How frequently should the questionnaire be reviewed?**
  Answer: It is recommended to regularly review the questionnaire, a yearly interval when the process is stable and well established is recommended.

- **Is it mandatory to complete the checklist?**
  Answer: The checklist is a tool to help in identifying possible issues in the disclosure process but its completion is not mandatory unless otherwise mandated by the <company>'s SOPs.

Disclosure process checklist

- **What to do when the responses to the questions in the checklist seem to suggest an issue in the disclosure process?**
  Answer: The checklist is a tool to help in identifying possible issues in the disclosure process but is not intended to deliver a final 'verdict' on the suitability of a <company>'s disclosure process. However, it is good practice to assess the impact and significance of any 'signal' detected through the checklist on the <company>'s disclosure process. If this assessment reveals that the signal detected is not relevant in the context of the process assessed, it is good practice to exclude the corresponding questions from the checklist and to keep a record of this decision.

- **Can the checklist be changed?**
  Answer: The checklist is a proposal but should be adapted to the needs and details of the disclosure processes assessed.

Disclosure trial task checklist

abpi
Bringing medicines to life

- **When should the questionnaire be completed?**
  Answer: It is recommended to complete it when there is a 'close to final' protocol. If through the checklist an issue in the protocol is detected this proactive completion allows the clinical team to initiate changes to the protocol before submission to the Independent Ethics Committee/Competent Authorities and thus avoiding the need of a formal protocol amendment.

- **Who should complete the questionnaire?**
  Answer: It is recommended that a senior member of the clinical team completes the checklist and that the person responsible for the disclosure process reviews it.

- **How frequently should the questionnaire be reviewed?**
  Answer: It is recommended to review the questionnaire prior to the implementation (and filing) of a protocol amendment, at completion of the trial or for longer-term studies at a yearly interval to ensure that disclosure obligations for the study have been made.

Disclosure trial task checklist

abpi
Bringing medicines to life

- **Is it mandatory to complete the checklist?**
  Answer: The checklist is a tool to help identify possible issues in the protocol in terms of compliance with disclosure obligations; however, its completion is not mandatory unless otherwise mandated by the <company>'s SOPs.

- **What to do when the responses to the questions in the checklist seem to suggest an issue in the protocol with regard to the <company>'s disclosure obligations?**
  Answer: The checklist is a tool to help in identifying possible issues in the protocol regarding disclosures' obligations but is not intended to deliver a final 'verdict' on the compliance of a protocol with regard to disclosures. However, it is good practice to assess the impact and significance of any 'signal' detected through the checklist on compliance with disclosure obligations.

- **Can the checklist be changed?**
  Answer: The checklist is a proposal and can be adapted to the needs and details of <company>'s disclosure rules.

Disclosure trial task checklist

abpi
Bringing medicines to life

- **What to do when the responses to the questions in the checklist seem to suggest an issue in the disclosure process?**
  Answer: The checklist is a tool to help in identifying possible issues in the disclosure process but is not intended to deliver a final 'verdict' on the suitability of a <company>'s disclosure process. However, it is good practice to assess the impact and significance of any 'signal' detected through the checklist on the <company>'s disclosure process. If this assessment reveals that the signal detected is not relevant in the context of the process assessed, it is good practice to exclude the corresponding questions from the checklist and to keep a record of this decision.

- **Can the checklist be changed?**
  Answer: The checklist is a proposal but should be adapted to the needs and details of disclosure processes assessed.

ABPI clinical trial disclosure toolkit disclaimer

The information provided in this toolkit for companies is provided in good faith, and every reasonable effort is made to ensure that it is accurate. The toolkit is not intended and should not be construed as regulatory or legal advice. The ABPI cannot in any circumstances accept responsibility for any errors or omissions and users should satisfy themselves as to their legal obligations.