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Template standard operating procedure on disclosure/transparency:

Self-training and Q&A materials

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Template standard operating procedure on disclosure/transparency:

Self-training materials

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What you need to know about this SOP

- **The template standard operating procedure (SOP) describes in detail the process, tasks and deliverables around the public disclosure of <company>'s clinical trials and their results.**
- **The SOP should be reviewed in conjunction with the <company>'s disclosure policy or equivalent document.**
- **It is also recommended to review position papers issued by IFPMA, EFPIA and the ABPI as they give background information on the industry's principles around transparency and disclosure.**
- **The ABPI disclosure toolkit web page also links to materials that provide additional background information on transparency and disclosure.**
- **Upon completion of the review of this SOP, determine what your role is, if any, in the disclosure of planned, ongoing or completed clinical trials and their results.**
- **This SOP also describes disclosure-related tasks when mergers and acquisitions, licensing deals have occurred or when an independent third party is involved in the disclosure process.**

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Key lessons

- In the disclosure community the publishing of information about clinical trials is often referred to as registration of a trial or registering a trial. The publishing of results of a clinical trial is often referred to as posting of results.
- For trials conducted in the European Economic Area (EEA) clinical trials are posted on EudraCT. At present the applicable National Competent Authority (NCA) manages the posting or registration on EudraCT.
- Publication of clinical trial information is prospective, ie needs to be completed at the latest when a clinical trial centre is initiated/first patient enrolled. However, more and more Independent Ethics Committees require evidence of posting on an WHO-recognised clinical trials registry as a condition of Independent Ethics Committee approval.
- In addition to EudraCT or the US trials registry (www.clinicaltrials.gov), many countries also require registration on a local/national portal/site.

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Key lessons

- **In globally operating companies, care must be applied to ensure that global disclosure processes and outputs also meet local (e.g. UK) disclosure obligations.**
- **The ABPI Code of Practice is clear on the need for posting results of clinical trials as referenced in the *Joint position on the disclosure of clinical trial information via Clinical Trial Registries and Databases* (updated 10 November 2009): www.pmcpa.org.uk/thecode/interactivecode/Pages/clause21.aspx#c21.1.**

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Key lessons

- To comply with industry best practices and company commitments, many companies rely on www.clinicaltrials.gov for registering trials that are carried out in territories where no local registration requirements or local portals exist.
- Most trial registries do not support the posting of results from clinical trials. Results of clinical trials can be posted on www.clinicaltrials.gov and EMA is updating their EudraCT database to allow it to act as a repository of clinical trials results.
- According to US law (FDAAA: Food and Drug Administration Amendments Act of 2007), results must be posted within one year of the trial completion date unless a certification for delaying submission of trials results is made, see – http://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhenDoINeedToRegister.
- Posting results on a portal such as www.clinicaltrials.gov is distinct from the publication of a scientific journal article/abstract or a conference abstract.

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Template SOP on disclosure/transparency:

Question and answers

Registering a clinical trial

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Please also consult the *Key lessons* section of this document.

- **Do all trials need to be registered on a portal/registry?**
  Answer: Applicable laws and regulations define the scope of disclosure. Generally, phase 1 trials in healthy volunteers do not need to be registered unless company policy mandates otherwise. However, from 30th Sept 2013 there is a UK requirement that all trials including phase 1 healthy volunteer studies be registered as a requirement for favourable REC opinion. For more information on how this will be implemented, see http://www.hra.nhs.uk/about-the-hra/who-we-are/transparency/

- **Is it mandatory to register a trial on www.clinicaltrials.gov?**
  Answer: Registration of a trial on www.clinicaltrials.gov is mandatory for trials that meet the FDAAA 801 definition of an 'applicable clinical trial' – see http://clinicaltrials.gov/ct2/manage-recs/fdaaa.

- **If a marketing authorisation is sought in the USA, is it mandatory to register a trial on www.clinicaltrials.gov?**
  Answer: Registration is mandatory for trials that meet the FDAAA 801 definition of an 'applicable clinical trial' – see http://clinicaltrials.gov/ct2/manage-recs/fdaaa.

Registering a clinical trial

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- **As a sponsor can we modify in EudraCT records related to clinical trials disclosure?**
  Answer: At present, only competent authorities (and not the sponsor) can make changes to EudraCT. However, with the planned extension in scope of EudraCT it is likely that sponsors will be more involved in this process.

- **If a trial is registered in EudraCT or www.clinicaltrials.gov, does the sponsor still need to register the trial on a local registry?**
  Answer: National laws or regulations state what needs to be done locally in terms of disclosure. If these mandate registration on a local registry then in the EU registration of the trial is needed locally and on EudraCT. If a trial is registered on a local WHO-recognised registry then registration on www.clinicaltrials.gov is not required.

Registering a clinical trial

- **If a trial is conducted together with another pharmaceutical company, do both companies need to register the trial?**
  Answer: No, but the contract between the two partners will need to define who takes responsibility for the disclosure tasks. Care will need to be taken in ensuring that responsibility for the updating of the relevant registries is clear. Frequently, the updating is managed through an interface between the company's clinical trial management system (CTMS) and the registry.

- **If a trial is conducted by an academic or collaborative group on behalf of a pharmaceutical company or the company provides the study drug, is the company responsible for registering the trial?**
  Answer: No, but the contract between the pharmaceutical company and the academic/ collaborative group will need to define who takes responsibility for the disclosure tasks.

Registering a clinical trial

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- **If the conduct of a trial is outsourced to a CRO can the sponsor delegate disclosure tasks to the CRO?**
  Answer: Yes, but the contract between the sponsor and the CRO will need to define the roles and responsibilities of the CRO and either in the contract or other binding agreement the methods of disclosure by the CRO must be described in detail.

- **Academic and some patients' advocacy groups also maintain clinical trials registries, does a sponsor also need to maintain trial information on these sites?**
  Answer: No, there is no legal or regulatory requirement to do so. However, Independent Ethics Committee as part of their conditions for approval could require this and companies may have committed in their disclosure policy to maintain such sites, when applicable.

Posting results of a clinical trial

Please also consult the *Key lessons* section of this document.

- **Do results of all clinical trials need to be posted on a public portal?**
  Answer: Yes for all clinical trials conducted in patients as referenced in the *Joint position on the disclosure of clinical trial information via Clinical Trial Registries and Databases* (updated 10 November 2009): www.pmcpa.org.uk/thecode/interactivecode/Pages/clause21.aspx#c21.1. The ABPI Code of Practice is clear on the need for posting results of clinical trials, results must be published within one year of marketing authorisation or one year from completion for marketed products.

- **Is it mandatory to post results of a trial on www.clinicaltrials.gov?**
  Answer: Posting of results is mandatory for trials that meet the FDAAA 801 definition of an 'applicable clinical trial' – see http://clinicaltrials.gov/ct2/manage-recs/fdaaa.

- **Do special requirements exist for trials in children?**
  Answer: In the EU there is a requirement that results of paediatric trials conducted in the EEA or are part of a Paediatric Investigation Plan (PIP) must be made public via EudraCT within six months of study completion.

Posting results of a clinical trial

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- **As a sponsor do I need to share the clinical study report with third parties such as the Cochrane Collaboration?**
  Answer: The Cochrane Collaboration is a private group and as such is not in scope of legislation or regulations such as FDAAA or EU regulations/directives/guidelines. However, it is up to individual companies to decide.

- **If an academic/collaborative group has conducted a trial with a product of my company, do we have an obligation to post the results?**
  Answer: The responsibility for posting results of a trial resides with the sponsor of the trial. If the academic/collaborative group has performed the trial with a commercially available product and without involvement of your company then the manufacturer has no responsibility in either the registration of the trial and/or posting of results. However, if the company supports the trial (e.g. by providing IMP, funding, etc.) then the contract between the parties involved needs to define their roles and responsibilities with regard to the disclosure and the timelines of disclosure of results.

Posting results of a clinical trial

- **If an academic/collaborative group has conducted a trial with a product of my company, can the manufacturer assume responsibility for the posting of the results of a trial?**
  Answer: This is possible as long as this agreed in a written contract where roles and responsibilities are clearly defined.

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.