Template standard operating procedure on clinical trial registry, results posting and publications

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Purpose

This document provides an overview of the process for posting clinical trial information on medicinal products on www.clinicaltrials.gov and other applicable portals for trials conducted (sponsored) or supported by <sponsor>.

In this document 'applicable trials' are the following:

- For clinical trials registry records: All Phase I clinical trials in patients, all Phase II – IV interventional and observational (non-interventional) studies, and interventional trials on advanced and launched medicinal products.
- For clinical results records: Phase I clinical trials in patients completed for marketed products, Phase II – IV interventional and observational (non-interventional) studies completed for marketed products.
- Any trial or result information that is required by local applicable laws or regulations.

Supported trials are clinical trials where <sponsor> only provides IMP or financial support to the sponsors of the trial but does not assume any sponsor responsibilities.

<Sponsor> supported trials will not be posted by <sponsor>. For supported trials, a contractual agreement between <sponsor> and supported entity must state when, how and where the details of the trial will be posted (eg on www.clinicaltrials.gov, a World Health Organization-accredited registry, etc) and the personnel responsible for the posting.

Document management aspects

Application area

Clinical Trials Phase I – IV at <Sponsor>

Governing documents

- IFPMA, 2005. *Joint position on the disclosure of clinical trial information via clinical trial registries and databases*
- IFPMA, 2009. *Joint position on the disclosure of clinical trial information via clinical trial registries and databases*. Updated 10 November 2009
- IFPMA, 2010. *Joint position on the publication of clinical trial results in the scientific literature*

Referenced documents

- ICMJE statement, *Uniform requirements for manuscripts submitted to biomedical journals*: *Publishing and editorial issues related to publication in biomedical journals*: *Obligation to register clinical trials*, www.icmje.org/publishing_10register.html
- *CONSORT Statement*, www.consort-statement.org/consort-statement
- *Good publication practice for pharmaceutical companies*
- FDA Amendments Act (FDAAA), Title IV & V
- EU, EudraCT (European Union Drug Regulating Authorities Clinical Trials) is the European Clinical Trials Database of all clinical trials commencing in the European Union from 1 May 2004 onwards. The EudraCT database has been established in accordance with Directive 2001/20/EC.
- UK Health Research Authority (HRA) http://www.hra.nhs.uk/resources/during-and-after-your-study/transparency-registration-and-publication/

- AMG, German Drug Act, and specifically the Drug Guideline (Arzneimittel-Richtlinie/ AM-RL) of 18 December 2008/22 January 2009, Art. 37.11

Replacing the following document(s)

Not applicable

Responsibilities

Author

<Name>

<Sponsor> Document owner

<Name>, <Job title>

Reviewers and approvers

Reviewer(s)

<Name>, <Job title>

Approver(s)

<Name>, <Job title>

Process

ID	Step	Description	Responsible
1.	**Setting up the infrastructure in <sponsor> to manage disclosure activities**		
1.1	Ensuring process and resources supporting disclosure activities are in place	Designate <function and individual> that takes responsibility for disclosure activities in <sponsor>. *Note: In the context of this SOP disclosure refers to the public posting of clinical trial information, as well as the public posting of results of clinical trials.* *In this SOP the individual who has overall responsibilities for disclosure activities in <sponsor> <or a business unit thereof> is referred to as the Disclosure Co-ordinator.* Agree with the Legal Counsel and <CEO><Head of Development><Medical Director> the principles of disclosure in <sponsor>. As a minimum, the following principles need to be defined upfront for all trials sponsored or supported by <sponsor>: *Disclosure of trials and studies* • Disclosure status of healthy volunteers' studies • Disclosure status of observational/ non-interventional studies • If the above trials are disclosed publicly timing of disclosure • Site of disclosure of clinical trials outside the European Economic Area (EEA) *Disclosure of results from trials and studies* • Timing of disclosure of results from interventional clinical trials and studies in patients. This will need to include a policy around the disclosure of results from trials with ○ non-approved medicinal products ○ New Molecular entity (NMEs) permanently discontinued from development ○ medicinal products that have a	<CEO><Head Development> <Medical Director> Disclosure Co-ordinator

		market authorisation anywhere in the world but have been investigated in a non-approved indication, population or dosage form, etc • Format of results disclosure *Note: sponsors can decide to post results on www.clinicaltrials.gov where results are to be posted in a semi-structured format or as ICH E3 summaries.* • Site of disclosure of results from interventional clinical trials and studies in patients. • Disclosure policy of results for healthy volunteers' studies and timing thereof. • Disclosure policy of results for observational/non-interventional studies and timing thereof. Approve the results disclosure policy of <sponsor>.	<CEO><Head of Development> <Medical Director>
1.2	Raising staff awareness in <sponsor> of its disclosure policy	Ensure new staff induction programmes include a review of <sponsor>'s disclosure policy and highlight the corresponding obligations. Provide training materials on disclosure to concerned functions. Ensure staff members are retrained when there are changes in <sponsor>'s disclosure policy.	Disclosure Co-ordinator
1.3	Implementing <sponsor>'s disclosure policy with business partners	Inform <sponsor>'s Legal Counsel of the disclosure requirements that any business partners must meet. *Note: Special scrutiny needs to be applied when <sponsor> supports a clinical trial conducted or sponsored by a third party or when an entire clinical programme or study is completely outsourced to a CRO or a partner.* Ensure that, where applicable, contract templates contain standard text illustrating the requirements in terms of disclosure.	Disclosure Co-ordinator Legal Counsel
1.4	Public interface and information of <sponsor>'s disclosure policy	Ensure that <sponsor>'s website home page includes a link to a section dedicated to the disclosure of clinical trial information. As a minimum, information on the	Disclosure Co-ordinator

		<sponsor> dedicated disclosure section on the website should include the following elements: • description of the disclosure policy for clinical trials • description of the disclosure policy for results from clinical trials • list of registries where comprehensive and exhaustive information about <sponsor>'s clinical trials activities and results thereof has been is being posted • company unique contact address for enquiries about clinical trials and related disclosure activities • description of <sponsor>'s QC and QA measures and processes to meet the goals and commitments of the *Joint industry position*. Ensure that questions or requests for information are managed in a timely manner and that requesters are given a complete response. *Note: The aim should be to provide at least a preliminary answer within two weeks and to communicate within that time frame the availability of the complete information.* Keep a log of all communication activities.	
1.5	<Sponsor>'s disclosure web pages	*Note: <sponsor> may decide to set up and maintain a company website where results from clinical trials can be posted in the form of ICH E3 summaries or equivalent format.* Decide whether clinical trial results should be disclosed on a <sponsor> web page in the format of <ICH E3 summary reports><indicate chosen format>. Ensure that the <sponsor> web page is set up in keeping with CSV (Computerised Systems' Validation) principles. Ensure the <sponsor> web page is kept up-to-date from a content and systems' requirements perspective. Ensure that content of <sponsor>'s web page is in line with official disclosure sites and in keeping with <sponsor>'s disclosure policy.	<CEO><Head of Development> <Medical Director> Disclosure Co-ordinator

1.6	Keeping the disclosure policy up-to-date	Ensure that <sponsor>'s disclosure policy is kept up-to-date with regulatory and legal requirements as well as industry standards. Keep a log of planned, initiated and completed disclosure policy updates.	Disclosure Co-ordinator
1.7	Keeping track of <sponsor>'s disclosure responsibilities	Develop metrics data to verify that disclosure activities with regard to the posting of clinical trials and their results globally are: • exhaustive and complete • timely • accurate. Review metrics data at least every <interval> and address with clinical teams and other concerned stakeholders any issues noted. Implement Corrective and Preventive Action (CAPA) plans to address issues noted.	Disclosure Co-ordinator
1.8	Ensuring quality in disclosure processes and disclosed information	Agree with the head <designated applicable group> Quality Assurance on a QA oversight programme. *Note: The QA oversight programme can include a variety of audits such as system audits, document audits, etc. These audits are planned and executed according to the applicable QA SOPs.* Share audit outcomes with concerned <sponsor> stakeholders and plan and execute coaching and training programmes, as appropriate.	Disclosure Co-ordinator

ID	Step	Description	Responsible
2.	**Disclosure aspects for UK affiliates of a multi-national company** *Note: The below requirements also apply to* a company with UK operations only and, if applicable, text should be adapted as suitable.		
2.1	Alignment of global and local (UK) disclosure processes	Assess whether global and UK disclosure processes are aligned and global processes and postings meet UK requirements. *Note: This requires that regulatory/legal or independent ethics committee as well as ABPI requirements can be met.* If applicable, implement a local (UK affiliate) process to complement global processes and outputs.	Disclosure Co-ordinator and UK Disclosures Responsible UK Disclosures Responsible
2.2	Meeting UK requirements for disclosure	Review HRA, MHRA, legislative and ABPI publications to keep up-to-date with changes to UK disclosure requirements. Update the UK policies and procedures, as appropriate. Follow the public debate on disclosure and transparency in the UK to proactively assess the need for an adaptation of the <sponsor> UK processes and procedures to maintain the public image of <sponsor> in UK Update and provide training to UK staff involved in clinical trials and disclosure activities.	UK Disclosures Responsible
2.3	Keeping track of <sponsor>'s disclosure responsibilities in the UK	Agree with the Disclosures Co-ordinator on the exchange of metrics data to verify that disclosure activities with regard to the posting of clinical trials and their results in UK are: • exhaustive and complete • timely • accurate. If indicated, complement the above metrics with locally generated data. Review metrics data at least every	UK Disclosures Responsible

		<interval> and address with clinical teams and other concerned stakeholders any issues noted. Implement Corrective and Preventive Action (CAPA) plans to address issues noted.	

ID	***Step***	***Description***	***Responsible***
3.	**Disclosure aspects when clinical trial activities are outsourced to a third party**		
3.1	Defining roles and responsibilities between <sponsor> and third party	Determine whether any disclosure activities should be strategically outsourced. Define boundaries between in- and out-sourced activities and tasks. If no strategic outsourcing has been implemented, at the latest when a 'robust protocol synopsis' is available agree on whether for a given protocol or clinical programme disclosure activities will be outsourced. *Note: Disclosure activities can be outsourced to an independent CRO or the CRO that also is responsible for study management or monitoring.*	Disclosure Co-ordinator and Head of Development Disclosure Co-ordinator and Clinical Team Representative
3.2	Assessing disclosure capability of third party	Develop a Request for Proposal (RfP) specifying competencies of potential third party service provider and deliverables for the disclosure tasks to be outsourced. *Note: If disclosures activities will be managed by the CRO that is also responsible for study management/ monitoring, then the above requirements will be incorporated into the pertinent RfP for the outsourcing of the trial.* Assess adequacy of responses to RfP for compliance with <sponsor>'s disclosure policy and processes.	Disclosure Co-ordinator
3.3	Contractual agreements	Ensure disclosure activities, deliverables and quality requirements are described in detail in the contract.	Disclosure Co-ordinator and Legal Counsel

		Ensure the contract with the third party is kept up-to-date.	
3.4	Overseeing disclosure activities of the third party	Agree with the relevant representative of the third party on the exchange of metrics data to verify that disclosure activities performed by the third party with regard to the posting of clinical trials and their results are: • exhaustive and complete • timely • accurate. Review metrics data at least every <interval> and address with the disclosure representative of the third party and other concerned stakeholders any issues noted.	Disclosure Co-ordinator

ID	***Step***	***Description***	***Responsible***
4.	**Disclosure aspects in the event of mergers, acquisitions, in- or out-licensing activities**		
4.1	Mergers and acquisitions	Ensure that the disclosure policies of the companies involved are reviewed, discrepancies in the policy identified and <the policies aligned><a new consolidated policy issued>. Approve the <consolidated><new> disclosure policy. Ensure all relevant stakeholders are informed about the requirements of the <consolidated><new> Disclosure policy. As a minimum inform <sponsor>'s Legal Counsel, <Head of Development,><Medical Director>, Head Regulatory Affairs, <Head of Public Affairs> and Head of IT. Provide training on the <consolidated><new> disclosure policy, see clause 1.2 of this SOP.	Disclosure Co-ordinator <CEO><Head of Development><Medical Director> Disclosure Co-ordinator
4.2	In- or out-licensing activities	Inform the Disclosure Co-ordinator of any planned in- or out-licensing deals. Ensure that the licensing partners are aware of disclosure requirements and make provisions that the rights, roles and responsibilities are unequivocally assigned to one of the partners.	Legal Counsel Disclosure Co-ordinator

ID	Step	Description	Responsible
		Specifically, ensure that future access to clinical trial data is clarified and that posting of results is in keeping with <sponsor>'s disclosure policy. Ensure the licensing agreement/contract reflects the above obligations.	Legal Counsel

ID	Step	Description	Responsible
5.	**Posting a new trial**		
5.1	Select applicable registries	Obtain from the study team the list of countries that will be possibly involved in the trial and select applicable registries where trial information is to be posted. Agree with the study team where results will be posted.	Disclosure Co-ordinator
5.2	Draft registry record	Contact the study team to obtain relevant information on the study (eg countries involved, current anticipated First Patient Enrolled ['FPI'] date, Health Authority and/or Institutional Review Board/Ethics Committee (IRB/EC) information if available). Ensure fields in internal database accurately reflect the study design and other essential data required by posting sites requirements of sites supported by <Sponsor>. Use relevant information from the protocol and/or draft protocol synopsis to complete the registry record.	Disclosure Co-ordinator
5.3	Send draft to reviewers	Export the draft registry record from database or draft posting record and forward to reviewers or designees for review and comment.	Disclosure Co-ordinator
5.4	Review registry draft	Review draft registry record and provide feedback, if needed. Send reviewed write-up back to Disclosure Co-ordinator	Reviewer

ID	Step	Description	Responsible
5.5	Include reviewers' corrections	Include comments and changes from Reviewer in registry record and in-house master document. After finalising registry record, send it to Reviewer for approval.	Disclosure Co-ordinator
5.6	Approve registry record	Approve the document with signature, either on paper, or electronically.	Reviewer
5.7	Post registry record	At the latest, after first IRB/EC and HA approval, post registry record. Address and follow-up on quality feedback comments from National Institutes of Health (NIH) review or other applicable body/bodies. If comments are substantial, consult reviewers for assistance with adjudication.	Disclosure Co-ordinator
5.8	Regular updating registry records	Update registry records as per registry business rules.	Disclosure Co-ordinator

ID	Step	Description	Responsible
6.	**Protocol amendment entry**		
6.1	Inform Disclosure Co-ordinator of amendment	In the event of substantial or significant protocol amendments (eg changes in subject eligibility criteria, study design, treatments, etc which would impact the registry summary), notify the Disclosure Co-ordinator and provide a copy of the amended protocol or protocol synopsis.	Study Leader
6.2	Review amendment	Review protocol amendment summary for significant changes in subject eligibility criteria, study design, treatments, etc and assess need to update in collaboration with the study team.	Disclosure Co-ordinator
6.3	Modify record	Modify registry record as necessary to reflect changes.	Disclosure Co-ordinator
6.4	Send record for review	If substantive changes have resulted from revisions, Disclosure Co-ordinator sends registry record to relevant reviewers or designees for review and comment	Disclosure Co-ordinator

6.5	**Continue with 5.4 – 5.8**		

ID	***Step***	***Description***	***Responsible***
7.	**Results posting process**		
7.1	Draft the results for www.clinicaltrials.gov or other applicable site	For results records to be posted on www.clinicaltrials.gov or other applicable site, use relevant information from the Clinical Study Report to complete the results record in www.clinicaltrials.gov or other posting site. *Note: If a company website is used to post results, eg as an ICH E3 summary, develop a procedure and process for the building, management and maintenance of the corresponding company website or refer to applicable company CSV SOPs. As for the posting of the results, proceed, as applicable, as per the steps described below.*	Disclosure Co-ordinator
7.2	Send draft to reviewers	Export the draft from www.clinicaltrials.gov or other applicable system and forward to reviewers or designees for comments.	Disclosure Co-ordinator
7.3	Review the results data	Review draft and forward comments to the Disclosure Co-ordinator.	Reviewer
7.4	Make changes to results data	Amend draft, if necessary, and send back to Reviewer for approval.	Disclosure Co-ordinator
7.5	Approve results posting	Approve draft in writing (paper or electronic signature) and send back to Disclosure Co-ordinator.	Reviewer
7.6	Post results record	Approve results record write-up in www.clinicaltrials.gov or other applicable system for posting. If applicable, address Quality Assurance (QA) comments from National Institutes of Health (NIH) or other applicable body review. If comments are substantial, consult reviewers for assistance with the final decision	Disclosure Co-ordinator

		Finalise posting of results.	
7.7	Managing posting of results	Review results record write-up and publication in journals/peer review journals for consistency.	Disclosure Co-ordinator

ID	***Step***	***Description***	***Responsible***
8.	**Publication of results from clinical studies at congresses or in internet fora**		
8.1	Selecting target audience and media	Decide if publication of results as a poster at a public venue (eg symposium, conference, congress or other non-peer reviewed vehicle) is anticipated as part of an overall publication plan. Assess whether such publication could negatively impact on the publication of results in a peer-reviewed Journal. *Note: Peer-reviewed journals may have strict rules about exclusivity of information presented and earlier publication of results or other key aspects of a clinical study such as a blog, poster, slide deck, etc could be interpreted by a Journal as previous publication and lead to the rejection of the manuscript. Presentations made to clinical study team members, advisory board members would not be considered as an early publication as long as materials shared are restricted to a limited group.*	Study Leader
8.2	Selecting the publication team	Upon consultation with the clinical and, if applicable, research team representatives decide about the authorship for the planned publication. Appoint a Lead Author. If more than one author contributes to the publication, decide on the sequence of the names of the authors in the published document. Assign an internal review team and a Lead Reviewer. The team should cover subject matter expertise that is relevant to the data to be presented	Study Leader
8.3	Delivering the	Write the article according to <sponsor>'s	Lead Author

ID	Step	Description	Responsible
	final product for publication	and publisher's style guide. The CONSORT Statement provides a standard way to report results from randomised controlled clinical trials and should be consulted: www.consort-statement.org Review the publication and ensure that the publication satisfies the following criteria: • Is non-promotional in tone • The primary and secondary outcome measures reflect the original protocol • Hypothesis generating statements are clearly identified as such • No <sponsor>-internal jargon and acronyms are used or they are explained in the text • Each author mentioned in the article had a clear role in the research/ clinical study • Information obtained from third party sources are clearly identified as such. Document completion of the review. Get final clearance for the publication from the Study Leader.	Lead Reviewer
8.4	Submitting the publication	Ensure that no ghostwriting occurs and individuals, who did not have a role in the gathering or analysis of the results to be published, are not mentioned as authors. Submit the publication in accordance with the requirements of the publishing body. Inform and send copy of the final manuscript as a minimum to the Study Leader, QPPV, Disclosure Responsible and Regulatory Officer.	Lead Author
8.5	Completing the publication process	Ensure that the publishers did not alter the manuscript in a manner that would change statements and tone of the publication. Update the manuscript as directed by the publisher but ensure that criteria defined in step 8.3 are still met.	Lead Author

ID	Step	Description	Responsible
		Inform individuals referred to in step 8.4 that the manuscript has been accepted and published. Ensure that a copy of the publication is filed in the Project Master File <and with Literature Services>.	

ID	Step	Description	Responsible
9.	**Publication of results from clinical studies in peer-reviewed journals**		
9.1	Selecting target audience and journal	Decide upfront, ie at the latest at study initiation • What criteria will be applied to select the article's authors, main author, last author, and sequence of any other contributors • Whether and when partial results, eg results from a single site, from a sub-study, will be published • Which journal will be targeted as a priority.	Study Leader
9.2	Developing and delivering the manuscript	Proceed as per steps 8.2 and 8.3	Lead Author and Lead Reviewer
9.3	Confirming the journal	Make final decision about the journal where the manuscript will be submitted. Develop a contingency scenario should the target journal refuse acceptance of the manuscript.	Study Leader
9.4	Submitting and finalising the publication process	Proceed as per steps 8.4 and 8.5	Lead Author and Lead Reviewer
9.5	Disseminating published article	Distribute published paper as per publication strategy.	Study Leader

Tracking of review, approval and effective dates and revision cycle of SOP and other key responsibilities

Version #	Activity/Task	Signature	Date
1.0	**Reviewed by:**		
	<Name>		
	<Position> (Job role)		
	Approved by:		
	<Name>		
	<Position> (Job role)		
	Distributed by:		
	<Name>		
	<Position> (Job role)		
	Training provided by[1]:		
	<Name>		
	<Position> (Job role)		
	<Name>		
	SOP effective on:		<Date>
	Revision due by:		<Date>
	Revision overseen / managed by:		
	<Name>		
	<Position> (Job role)		

[1] The date for training is the date by which the training needs to be completed. Training logs will be maintained as per Training SOP.

ABPI clinical trial disclosure toolkit disclaimer

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