Process checklist – results disclosure

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Process checklist – results disclosure

Company:	**[Company Name]**
Year:	**201[x]**

This checklist should help sponsors and their teams or disclosure group to avoid common pitfalls and errors when setting up the process for the disclosure of clinical trial results. The intention of this checklist is not to replace a standard operating procedure (SOP) or to be used as presented as a routine quality control (QC) tool. However, elements of this checklist can be used to construct a routine QC tool supporting the disclosure process of trial results. It is recommended that each user first analyses their disclosure process and constructs a meaningful QC tool accordingly.

This part of the checklist addresses the management of the posting of clinical trial results.

Note: Management of entries in EudraCT is not addressed in this checklist as this is currently a task under the control of the concerned competent authority.

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Setting up the disclosure process and system				
Process steps	**Disclosure task/deliverable**	**Check parameters**	**Applies**	**Does not apply**
Deciding on the clinical trial results disclosure policy	Determine the regulatory, legal and company policy requirements for the posting of clinical trial results	Trials that are required to be disclosed by national/applicable legislation such as HRA, EMA and FDAAA (ie drug/biologic/device research in which subjects/patients are assigned to specific interventions according to a study protocol)		
		Trials to be disclosed by ICMJE requirements (ie drug/biologic/device/ surgical procedures/behavioural/ treatment/dietary intervention/process of care change research in which subjects/patients are assigned to specific interventions according to a study protocol.		

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		Observational trials (ie drug/biologic/ device is administered/provided to a patient as part of routine medical care [eg researcher does not assign intervention, but reviews patient records to assess certain effects/impacts or to collect longitudinal data to track health outcomes])		
		Based on International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Pharmaceutical Research and Manufacturers of America (PhRMA), European Federation of Pharmaceutical Industries and Associations (EFPIA) and/or Japan Pharmaceutical Manufacturers Association (JPMA) joint position statement		
		Other arrangements made [Specify:]		
Selection of public site of clinical trial results disclosure	Determine what systems and tools are available to the company, and make the selection accordingly.	All results posted on www.clinicaltrials.gov		

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		Only results of trials that are in scope of FDAAA posted on www.clinicaltrials.gov		
		Posting of results of trials on www.clinicaltrials.gov not required		
		All results posted on company website		
		Results posted to country/region specific database/portal/website		
		Other arrangements made [Specify:]		
Company's approach to clinical trial results disclosure	Operational model for managing disclosure of clinical trials	A dedicated disclosure group manages all tasks		
		A dedicated disclosure group manages the following task, [specify]		
		A dedicated disclosure group manages tasks for trials of the following phases or type, [specify]		
		Disclosure activities are managed by the clinical team		

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		Disclosure activities are outsourced to a third party		
		A hybrid operations model is implemented, [briefly describe delegation of tasks]		
		Dedicated budget available to address clinical trial results disclosure activities needs		
	A dedicated group is responsible for the operational tasks of disclosure	Group belongs to Medical Writing		
		Group belongs to Regulatory Affairs		
		Group belongs to Clinical Operations		
		Group belongs to Medical Affairs		
		Group belongs to Legal		
		Group belongs to Corporate Communication		
		Group belongs to ‘Other’, [specify:]		

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Keeping track of changes in clinical trial results disclosure requirements	Surveying changes in disclosure requirements such as FDAAA and global requirements (including US and excluding US)	Manual identification of each region/country specific requirement with internal resources		
		Subscription to any online knowledge database on transparency requirements		
		Outsourced resources		
		Other arrangements made [Specify:]		
Standards for results disclosure activities	SOPs	Written policy and/or standard operating procedures for clinical trial results disclosure is in place		
	Management review	A Steering Committee oversees performance of disclosure activities		
	Dictionaries	To report adverse event data a standard dictionary such as MedDRA is used		
		To report adverse event data a standard dictionary such as Snomed is used		
		To report adverse event data a standard dictionary such as WHOART is used		
		To report adverse event data a standard dictionary such as COSTART is used		

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	Source data	The SOP unequivocally designates what is the reference or source document for results disclosure outputs		
Training	Training company stakeholders on clinical trial results disclosure	A formalised training programme is in place to identify staff newly exposed to disclosure activities and to train them		
		Training is also an on-going activity		
		Training is also addressing impact of non-compliance		
		Training of staff is an ad-hoc activity		
		Other arrangements made [Specify:]		
Managing disclosure				
Process steps	**Disclosure task/deliverable**	**Check parameters**	**Applies**	**Does not apply**
Policy on the preparation of results postings	Timing of preparing results disclosure records? (Select all that apply)	When protocol is finalised but before clinical study report is drafted		
		During draft stages of clinical study report but before it is finalised		

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		After clinical study report is finalised		
		When the primary manuscript is being developed		
		When the primary manuscript is finalised		
		Other arrangements made [Specify:]		
Ensuring disclosure commitments are fulfilled				
Process steps	**Disclosure task/deliverable**	**Check parameters**	**Applies**	**Does not apply**
Standards	Data management manual for results disclosure	A manual or standard is in place to capture data entry rules and conventions		
QC approach	Review of results postings	Formal cross-check data for consistency between publications and data posted on registries is part of 'Disclosure SOP'		
		Formal cross-check data for consistency between clinical study report and data posted on registries is part of 'Disclosure		

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		SOP'		
		No formal cross-check but ad-hoc cross-check process		
		Posting outputs generated through a manual 'copy and paste' from clinical study report contents		
		Technology used to generate posting outputs, eg content management tools used		
		Other arrangements made [Specify:]		
	Performance metrics	Performance metrics are defined and implemented		
		Performance metrics covers date results are posted on the applicable disclosure site vs. Last Patient Last Visit (LPLV)		
		Time for submitting record into disclosures database/registry to public release by disclosure database/registry		
		Number of review cycles, internal review		

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		Number of review cycles, by posting registry		
		Number of records released with no/minor comments from disclosure database/registry review		
		Number of disclosed records with no critical incompliance in terms of disclosure database/registry business rules		
		Number of records for delayed posting		
		Delayed posting, number of records meeting adjusted timelines		

ABPI clinical trial disclosure toolkit disclaimer

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