Process checklist – clinical trial registries

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Process checklist – clinical trial registries	
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 disclosing information about new clinical trials. The intention of this checklist is not to replace a standard operating procedure (SOP) or to be used as presented as a routine QC tool. However, elements of this checklist can be used to construct a routine QC tool supporting the disclosure process. It is recommended that each user first analyses its disclosure process and constructs a meaningful QC tool accordingly.

This part of the checklist addresses the process for the management of the posting of new clinical trials information within registries.

Note: Management of entries in EudraCT is not addressed in this checklist as this is currently part of the Clinical Trial Application and management process and is 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 disclosure policy	Determine the regulatory, legal and company policy requirements for the posting of clinical trials.	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 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 disclosure	Operational model for managing disclosure of clinical trials	A dedicated disclosure group manages all tasks		
		A dedicated disclosure group manages the following tasks, [specify]		
		A dedicated disclosure group manages tasks for trials of the following phases or type, [specify]		
		Disclosures activities are managed by the clinical team		
		Disclosure activities are outsourced to a third party		

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		A hybrid operations model is implemented, [briefly describe delegation of tasks]		
		Dedicated budget available to address clinical trial 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		
		Other, [specify:]		
Keeping track of changes in clinical trials 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		

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		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		
	Source data	The SOP unequivocally designates the protocol as the reference or source document for clinical trial disclosure postings		
	Management review	A steering committee oversees performance of disclosure activities		
Training	Training company stakeholders of clinical trial results disclosure	A formalised training programme is in place to identify staff newly exposed to disclosure activities and to train them		
		Training of staff is an ad-hoc activity		
		Training is also an on-going activity		
		Training is also addressing impact of non-compliance		
		Other arrangements made [Specify:]		
Data transfer	Initiating a registry posting	Data is electronically uploaded to the applicable registries via PRS		

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		Data is electronically uploaded to the applicable registries via XML upload		
		Data is electronically uploaded to the applicable registries via other uploading mechanism, [specify]		
		Data is electronically uploaded to www.clinicaltrials.gov, as a minimum		
		Data is manually uploaded to the applicable registries		
		Initial entry is performed by a contracted third party		

Managing disclosure

Process steps	Disclosure task/deliverable	Check parameters	Applies	Does not apply
Data transfer	Updating a registry posting with clinical trial operational data such as enrolment status, site initiation, site closure, etc	Data is electronically uploaded to the applicable registries		
		Data is electronically uploaded to www.clinicaltrials.gov, as a minimum		

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		Data is manually uploaded to the applicable registries		
		Update is performed by a contracted third party		
Ensuring disclosure commitments are fulfilled				
Process steps	**Disclosure task/deliverable**	**Check parameters**	**Applies**	**Does not apply**
Standards	Data management manual for clinical trial postings	A manual or standard is in place to capture data entry rules and conventions		
QC approach	Review of clinical trial registry postings	Formal cross-check data for consistency between protocol and data posted on registries is part of 'Disclosure SOP'		
		No formal cross-check but ad-hoc cross-check process		
		Posting outputs generated through a manual 'copy and paste' from protocol contents		
		Technology used to generate posting outputs, eg content management tools used		

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		Other arrangements made [Specify:]		
	Performance metrics	Performance metrics are defined and implemented		
		Performance metrics covers date protocol first filed with Health Authorities or Independent Ethics Committee vs. date protocol is registered on the applicable registries		
		Performance metrics covers date first patient recruited vs. entry on applicable registries		
		Performance metrics covers projected date last patient recruited (no longer enrolling) vs. entry on applicable registries		
		Performance metrics covers date last patient recruited vs. entry on applicable registries		
		Performance metrics covers date Registry is updated to reflect closed recruitment status vs. entry on applicable registries		
		Performance metrics covers date projected Last Patient Last Visit (LPLV) vs. entry on applicable registries		

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		Performance metrics covers date LPLV vs. entry on applicable registries		
		Performance metrics covers date the trial is completed vs. entry on applicable registries		
		Number of review cycles, internal review		
		Number of review cycles, by posting registry		
		Number of review cycles, internal review		
		Number of review cycles, by posting registry		
		Number of records released with no/minor comments from registry review		
		Number of disclosed records with no critical incompliance in terms of registry business rules		

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