Task checklist – results disclosure

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Bringing medicines to life

Task 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 disclosing information about 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.

Task checklist – results disclosure

Initial disclosure of the results of clinical trials			
Process steps	**Check parameters**	**Applies**	**Does not apply**
Initial disclosure of the results of clinical trial	All results posted on www.clinicaltrials.gov		
	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 specified database/portal/website		
	Other arrangements made [Specify:]		
Managing disclosure of results			
Process steps	**Check parameters**	**Applies**	**Does not apply**

Task checklist – results disclosure

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 within defined timeframe, [specify defined timeframe]		
	Data is electronically uploaded to www.clinicaltrials.gov within defined timeframe, [specify defined timeframe]		
Training	Training and re-training delivered on time		
Ensuring disclosure commitments are fulfilled			
Process steps	**Check parameters**	**Applies**	**Does not apply**
Review of results	Formal cross-check data for consistency between publications and data posted on registries meets requirements of 'Disclosure SOP'		

Task checklist – results disclosure

postings	Formal cross-check data for consistency between clinical study report and data posted on registries meets requirements of 'Disclosure SOP'		
	Other QC checks carried out [Specify:]		
Performance metrics	Performance metrics within defined targets		
	Date results posted on the applicable disclosure site within defined timelines of Last Patient Last Visit (LPLV). [Specify target timelines: ….. days]		
	Time from submitting record into disclosures database/registry to public release by disclosure database/registry within defined timelines of LPLV. [Specify target timelines: ….. Days]		
	Number of review cycles, internal review within target [Specify target number of max target timelines …… cycles]		
	Number of review cycles, by posting registry [Specify target number of max target timelines …… cycles]		
	Number of records released with no/minor comments from disclosure database / registry review [Specify max. number of records within target … …number of records]		

Task checklist – results disclosure

	Number of disclosed records with no critical non-compliance in terms of disclosure database/ registry business rules [Specify max. number of records within target …… number of records]		
	Delayed posting, number of records meeting adjusted timelines [Specify max. number of records meeting adjusted timelines …… number of records]		

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