

# Task checklist – trial registration

Task checklist – trial registration	
<b>Company:</b>	[Company Name]
<b>Year:</b>	201[x]
<p>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 its disclosure process and constructs a meaningful QC tool accordingly.</p> <p>This part of the checklist addresses the management of the registration of a clinical trial.</p> <p>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.</p>	

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Initial disclosure of a clinical trial		
Clinical trial registries that are in scope and applied have been identified	<a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a>	
	EudraCT	
	Local registries, [specify]	

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Managing the disclosure of a trial		
<b>Updating a registry posting with clinical trial operational data such as enrolment status, site initiation, site closure, etc</b>	Data is electronically uploaded to the applicable registries within defined time frame, [specify defined timeframe]	
	Data is electronically uploaded to <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a> within defined time frame, [specify defined timeframe]	
	Clinical trial registered on all applicable registries	
	<a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a>	
	EudraCT	
	Local registries, [specify]	
	Local registries, [specify]	
	Local registries, [specify]	

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	Local registries, [specify]	
	Local registries, [specify]	
<b>Training</b>	Training and re-training delivered on time	

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<b>Ensuring disclosure commitments are fulfilled</b>		
<b>Review of clinical trial registry postings</b>	Formal cross-check data for consistency between protocol and data posted on registries within set limits	
	Other QC checks carried out [Specify]:	
<b>Performance metrics</b>	Performance metrics within set limits	
	Performance metrics date protocol first filed with Health Authorities or Independent Ethics Committee vs. date protocol is registered on the applicable registries	
	Performance metrics, date first patient recruited vs. entry on applicable registries within set limits	
	Performance metrics, projected date last patient recruited (no longer enrolling) vs. entry on applicable registries within set limits	
	Performance metrics, date last patient recruited vs. entry on applicable registries within set limits	
	Performance metrics, date registry is updated to reflect closed recruitment status vs. entry on applicable registries within set limits	
	Performance metrics, date projected last patient – Last Patient Last Visit (LPLV) vs. entry on applicable registries within set limits	

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

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