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Process flow maps:

Clinical trial registration and results disclosure process

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Process flow maps:

Clinical trial registration process

Standard notification for process flow maps

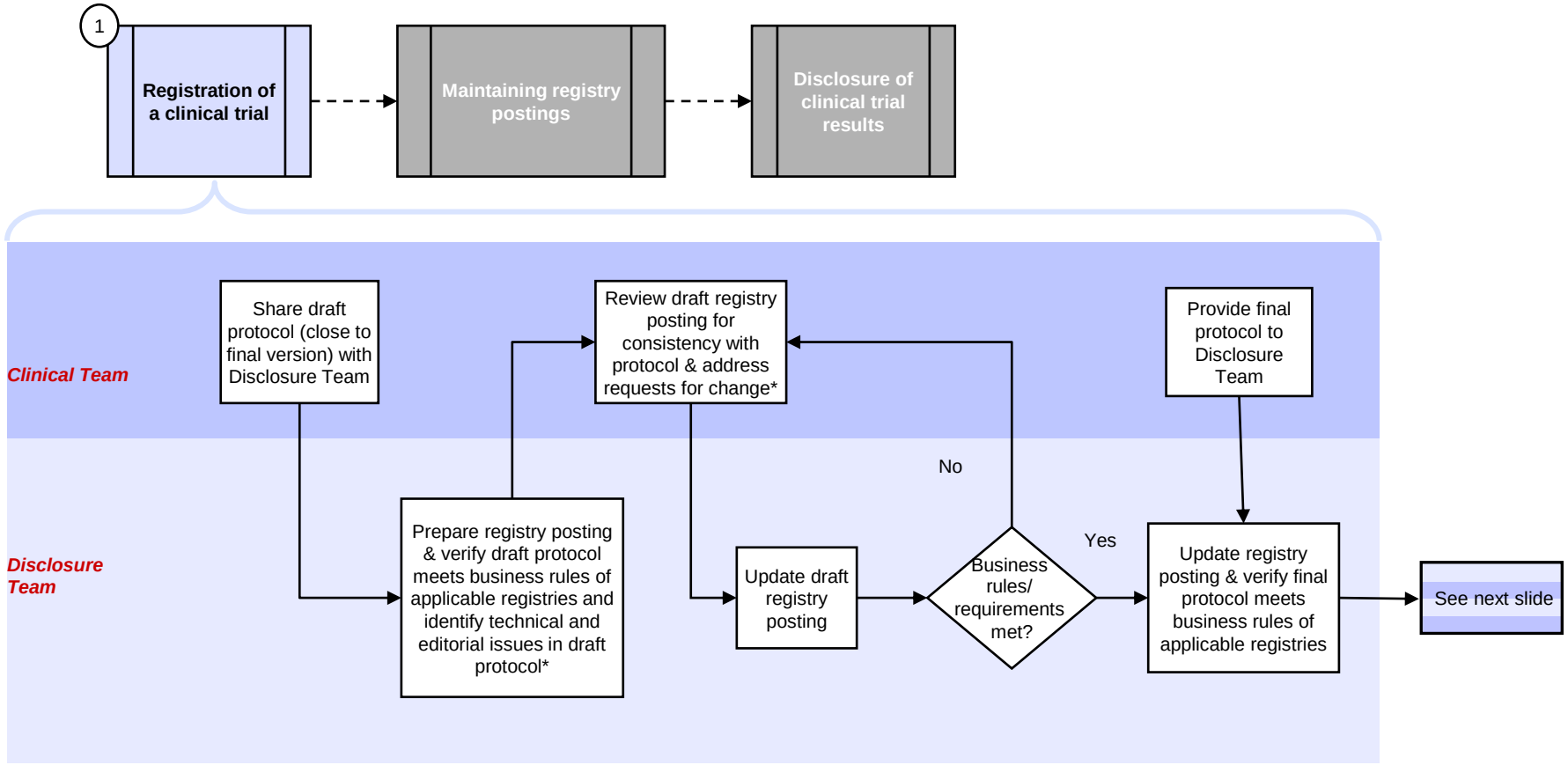
	Arrows indicating direction to next process
	Arrows indicating direction to next process step
	Process
	Process step
	Process step indicating a decision
	Process step signaling an end of a process
	Input: Process triggering next process step
	Output: Process followed after previous process step

Process assumptions

- **The company has a disclosure process in place.**
- **The steps on the following pages are based on the assumption that the company's process is followed.**
- **The company policy/SOP or other company guidelines define:**
  - which trials or type of trials are in scope of the company's disclosure policy
  - which registries/disclosure databases are to be managed
  - what timelines apply for disclosure of new clinical trials and results of these trials
  - the data flow for initiating and maintaining the disclosure process
  - roles and responsibilities for disclosure tasks.
- **If the company maintains a dedicated website to disclose results of clinical trials, the company has documentation for the systems in use and a risk assessment with regard to compliance with Computerised Systems' Validation (CSV) requirements.**
- **For results of clinical trials the workflow covers posting of an ICH E3 summary as well as of registry-defined structured outputs.**

Registration of a clinical trial (Part 1)

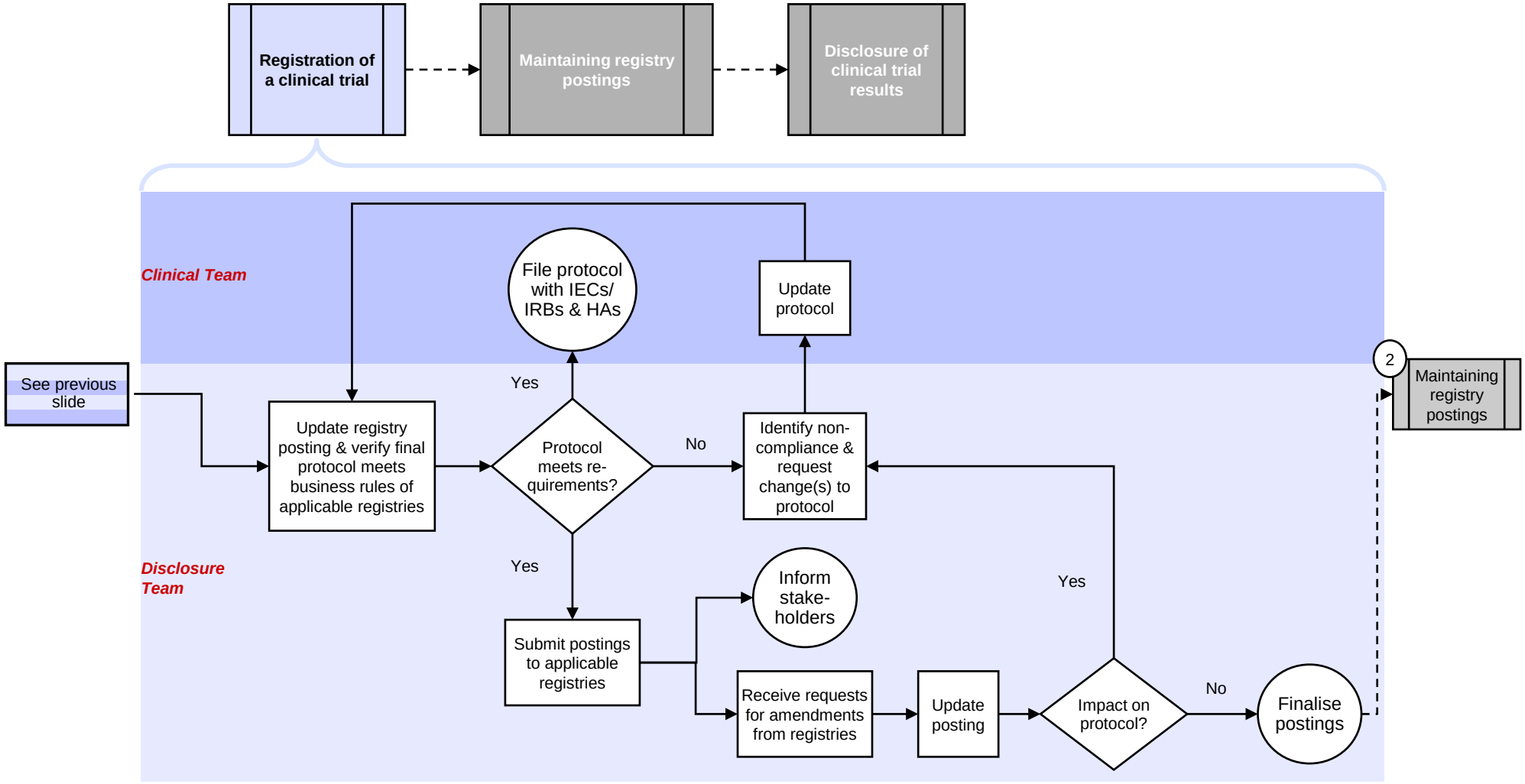
(Process described is a possible flow and should not be viewed as a mandatory process)



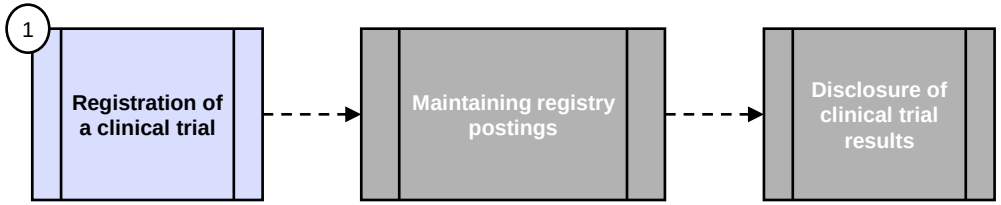
- *Responsibility and task assigned as per company SOP*

Registration of a clinical trial (Part 2)

(Process described is a possible flow and should not be viewed as a mandatory process)



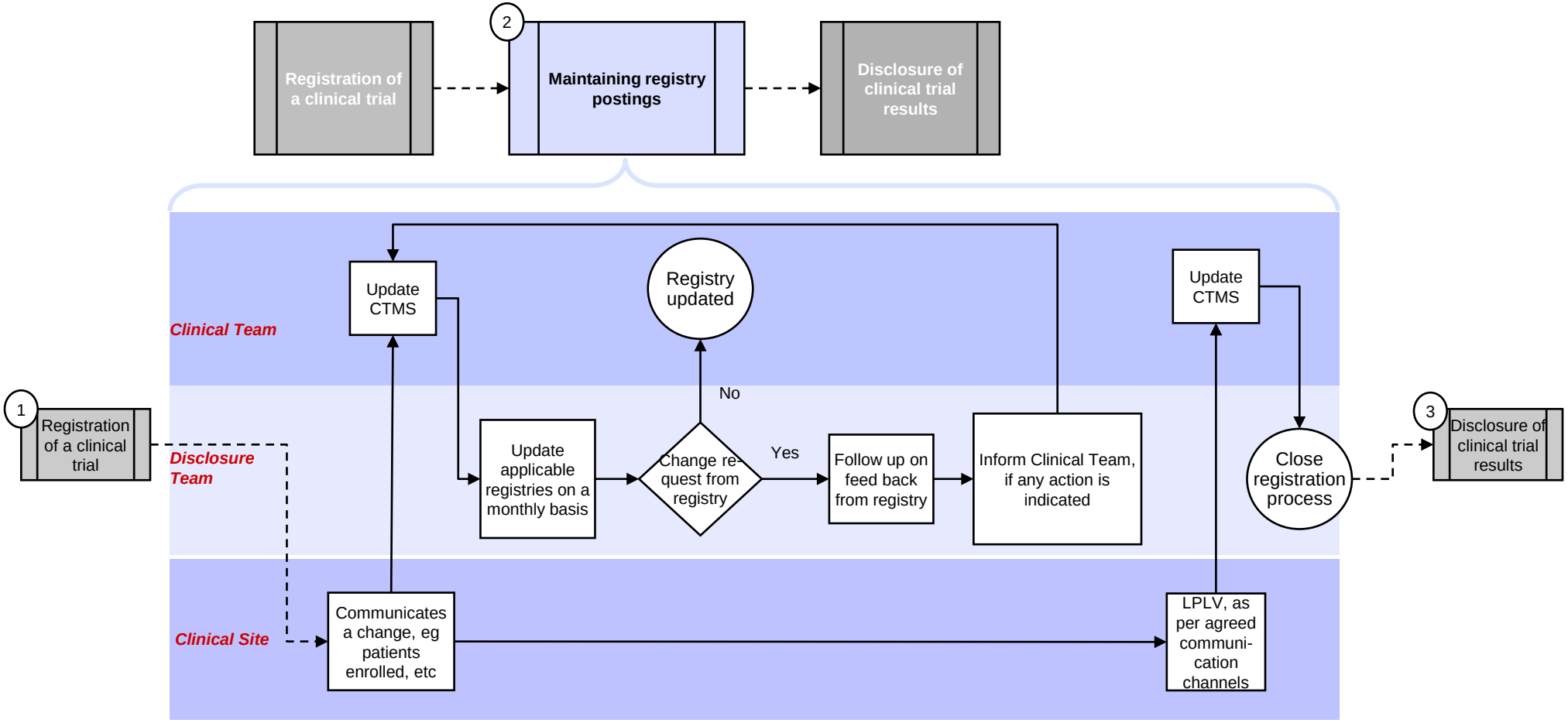
Registration of a clinical trial



Responsible Party	Procedure
Clinical Team	▸ Informs the Disclosure Team of the close-to-final protocol ▸ Reviews the draft registry posting prepared by the Disclosure Team ▸ Finalises the protocol and communicates this to the Disclosure Team ▸ Updates the protocol, if applicable ▸ Files the protocol with IECs/IRBs and Health Authorities as per applicable regulations
Disclosure Team	▸ Prepares the registry posting and identifies protocol issues in terms of applicable registry business rules and identifies technical and editorial inconsistencies in the protocol ▸ Updates draft registry posting based on input received from Clinical Team ▸ Verifies feedback received is consistent with applicable registries business rules ▸ Updates registry posting and verifies final protocol meets business rules of applicable registries ▸ Submits postings to applicable registries ▸ Identifies non-compliance with registry business rules and requests changes to protocol ▸ Follows up on feedback received from registries ▸ Updates postings ▸ Informs company stakeholders of completed postings as per applicable SOP

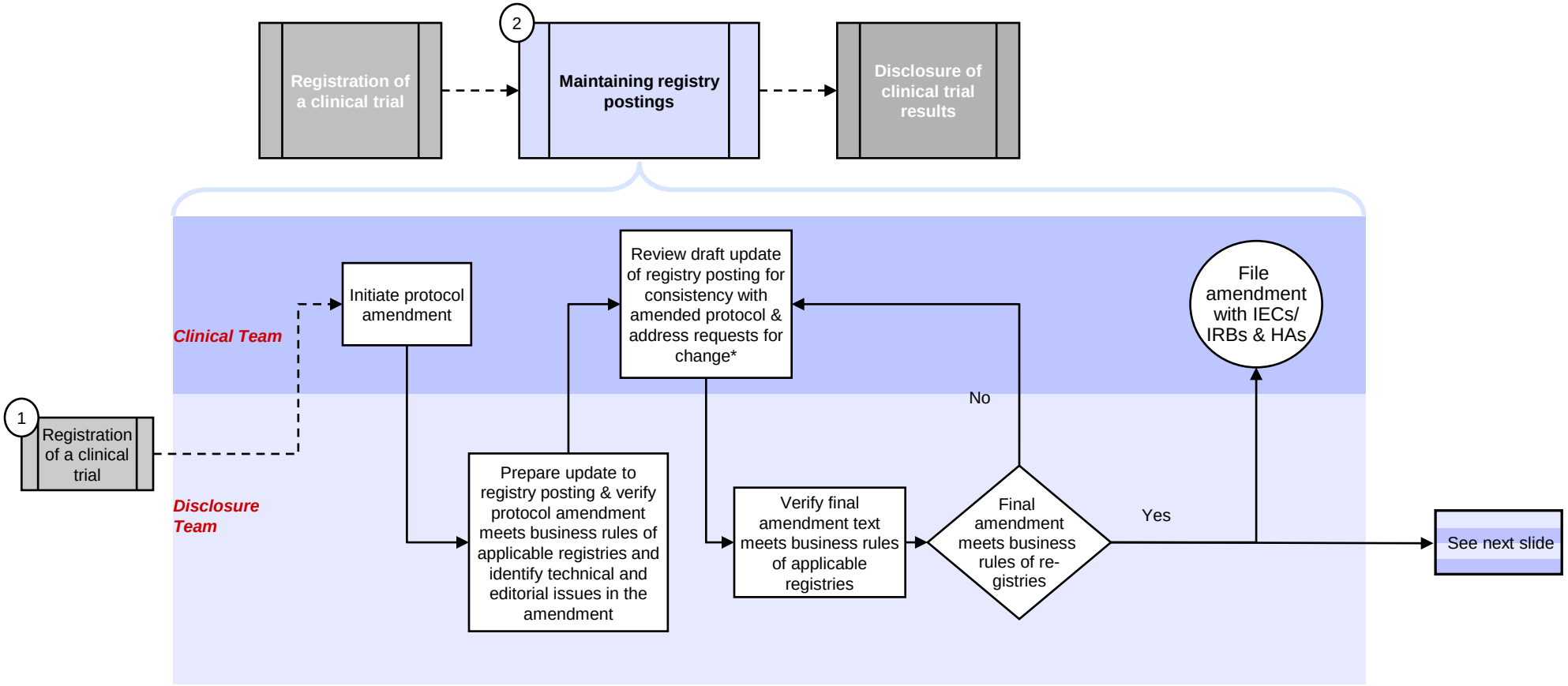
Maintaining registry postings

(Applicable updates to registries such as www.clinicaltrials.gov, etc)



Managing protocol amendments & registry postings (Part 1)

(Process described is a possible flow and should not be viewed as a mandatory process)



- *Responsibility and task assigned as per company SOP*

Managing protocol amendments & registry postings (Part 2)

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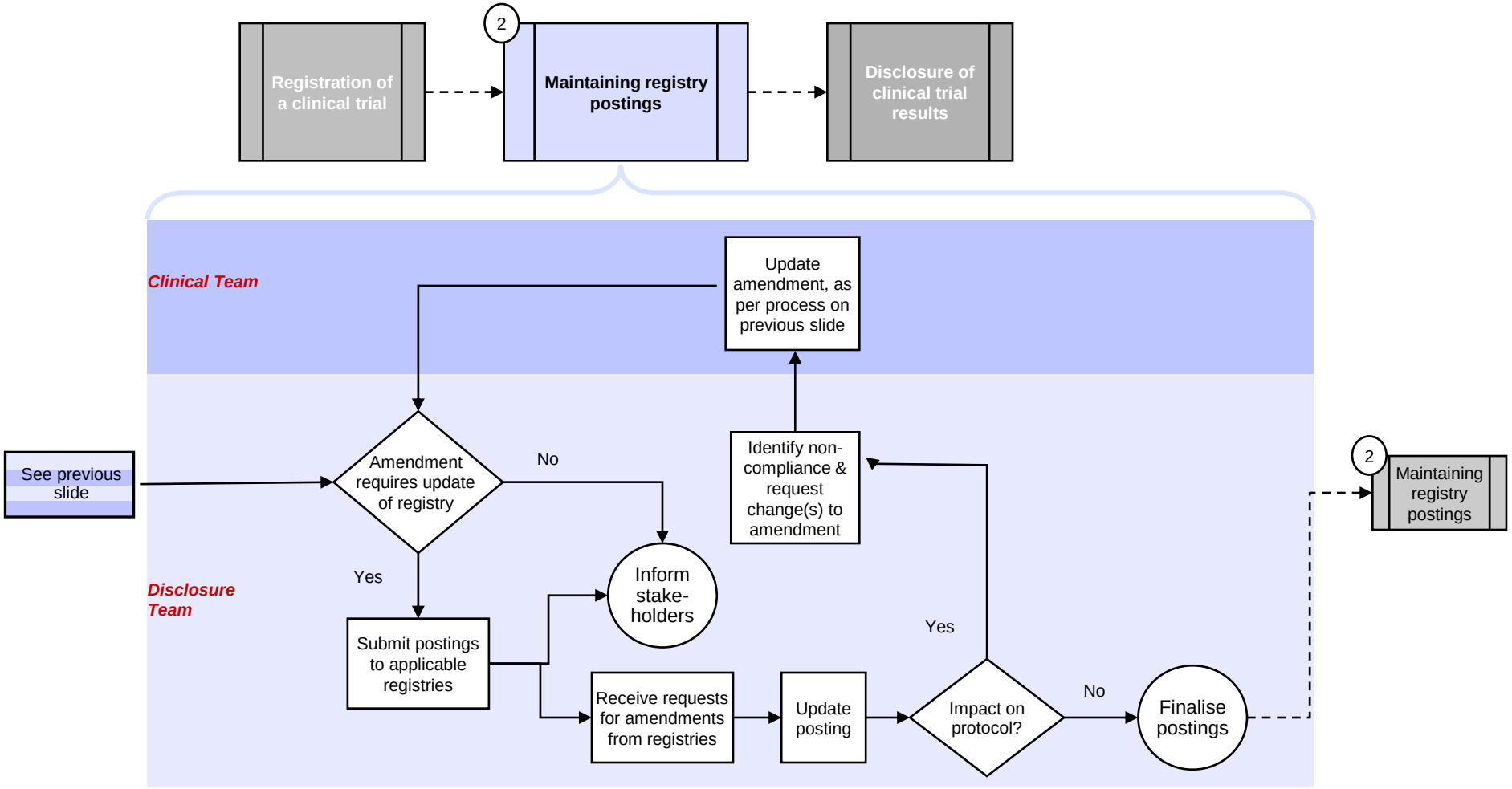
(Process described is a possible flow and should not be viewed as a mandatory process)



Maintaining registry postings

Responsible Party	Procedure
Clinical Team	▸ Updates CTMS according to progress report from clinical sites ▸ Amend protocol, if applicable on feedback from Disclosure Team
Disclosure Team	▸ Updates registries with new information from clinical sites through CTMS ▸ Follow-up on feedback received from registries ▸ Assess impact of amendment on information disclosed on applicable registries ▸ Update registry entry, if applicable ▸ Communicate to Clinical Team change to registry following a protocol amendment
Clinical Site	▸ Communicates progress on the study, eg number of patients enrolled and others ▸ Communicates LPLV via updates to CTMS (either through the monitor or by directly updating the CTMS)

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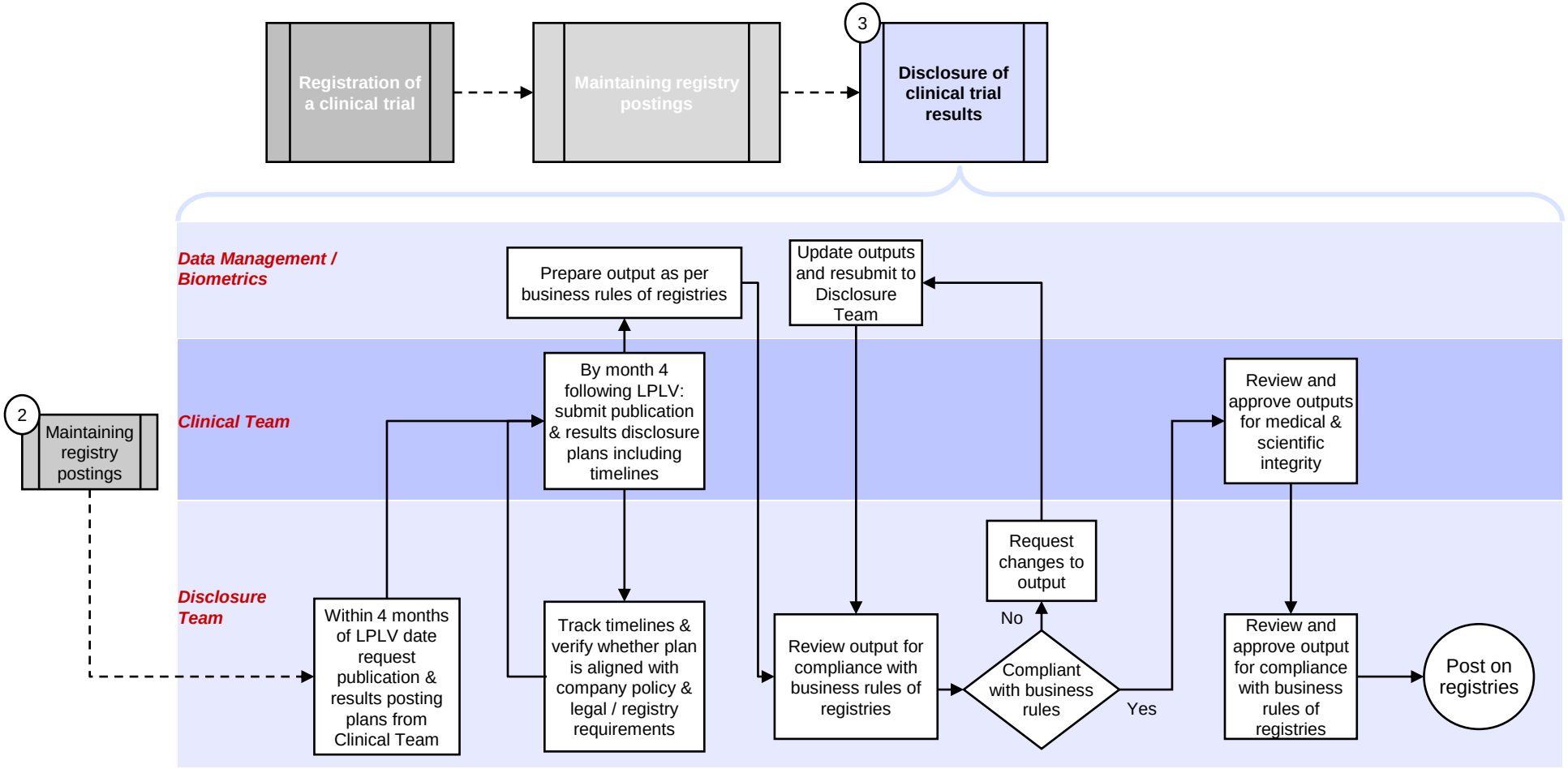
Process flow maps:

Results disclosure process

Disclosure of clinical trial results (structured/tabular outputs)

(Managing disclosure of results on registries requiring structured/tabular outputs, eg www.clinicaltrials.gov)



Disclosure of clinical trial results as ICH E3 summaries

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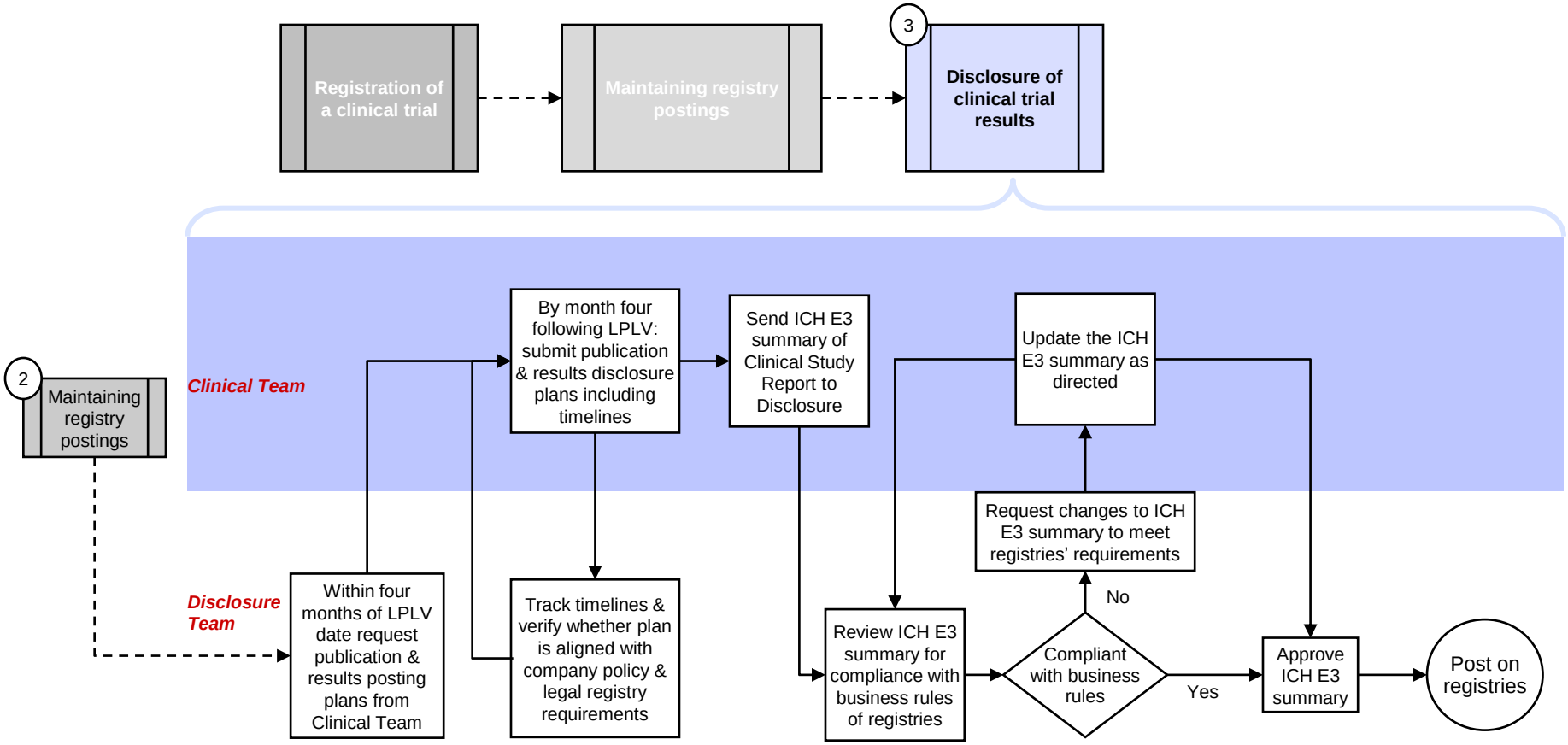
(Managing disclosure of results on registries)



Disclosure of clinical trial results

Responsible party	Procedure
Clinical Team	▸ Submit publication and results disclosure plans including timelines to Disclosure Team ▸ If applicable, send ICH E3 summary of clinical study report to Disclosure Team ▸ Update ICH E3 summary on feed back from Disclosure Team ▸ Review and approve output from Data Management for medical and scientific integrity
Disclosure Team	▸ Request publication and results posting plans from Clinical Team ▸ Track timelines and verify whether plan is aligned with company policy & legal/registries' requirements ▸ Remind Clinical Team of timelines ▸ Review and approve output from data management for compliance with registry business rules ▸ Post output on applicable registry ▸ If applicable, review ICH E3 summary for compliance with business rules of applicable registry and ▸ If applicable, approve ICH E3 summary and post on applicable registry
Data Management/ Biometrics	▸ Prepare output as per business rules of applicable registries

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