Clinical Trial Transparency Infosheet

Charité – BIH Clinical Study Center (CSC)

REGISTRY

Register prospectively

registration is required in a WHO ICTRP registry **before** enrollment of first patient

guideline
(WMA, ICMJE, WHO, QM-Handbuch)

law (CTIMP trials)
EU 536/2014, EU 2017/745

Upload summary results

<1 year (WHO, BMBF, CTIMP)
<2 years (DFG)

after trial completion

guideline
(WHO, BMBF, DFG)

law (CTIMP trials)
2012/C 302/03 (EU)

Link to results publication(s)

all trial publications should be linked in the registration

guideline
(WHO)

PUBLICATION

Publish results in a journal

<2 years

after trial completion

guideline
(WHO, BMBF, DFG)

Make publication(s) openly accessible

publications describing clinical trial results should be open access, wherever possible

guideline
(WHO)

Include the trial registration number

the trial registration number (TRN) should be reported in the publication **abstract** and **main body**

guideline
(CONSORT, ICMJE, WHO)

Abbreviations

CONSORT	Consolidated Standards of Reporting Trials
CTIMP	Clinical Trial of an Investigational Medicinal Product
DRKS	Deutsches Register Klinischer Studien
EudraCT	EU Drug Regulating Authorities Clinical Trials Database
FDAAA	Food and Drug Administration Amendments Act of 2007
ICMJE	International Committee of Medical Journal Editors
ICTRP	International Clinical Trials Registry Platform
WHO	World Health Organization
WMA	World Medical Association

Registry Notes

- **EudraCT:** Applies to CTIMPs. The Charité Clinical Study Center is your point of contact for support for registration and reporting in EudraCT: studienergebnisse@charite.de
- **DRKS:** Except for CTIMPS, the Charité recommends the German Register for Clinical Trials, which is linked to the ICTRP of the WHO (see the Charité QM-Handbuch).
- **ClinicalTrials.gov:** Generally if a trial has a location in the United States. Even if conducted entirely outside the United States, a trial may still be subject to the FDAAA and Final Rule.

GENERAL RESOURCES

Where should I register a trial?

A trial should be registered in a single registry, except if strictly necessary, e.g., legal or funder requirements. If a trial is registered in multiple registries, transparency practices should be adhered to across registries. More information.

How do I register a trial? *

ClinicalTrials.gov, **OR**
DRKS, **OR**
EudraCT (CTIMP trials)

How do I post summary results in the registry? *

ClinicalTrials.gov
DRKS
EudraCT (CTIMP trials)

How do I link a publication in the registry? *

ClinicalTrials.gov
DRKS

How do I make a publication openly accessible?

- Publish Open Access, **OR**
- After publication: make a version of the publication openly accessible in a repository (visit Shareyourpaper or contact the Charité OA team)

* Select the resource for the applicable registry.