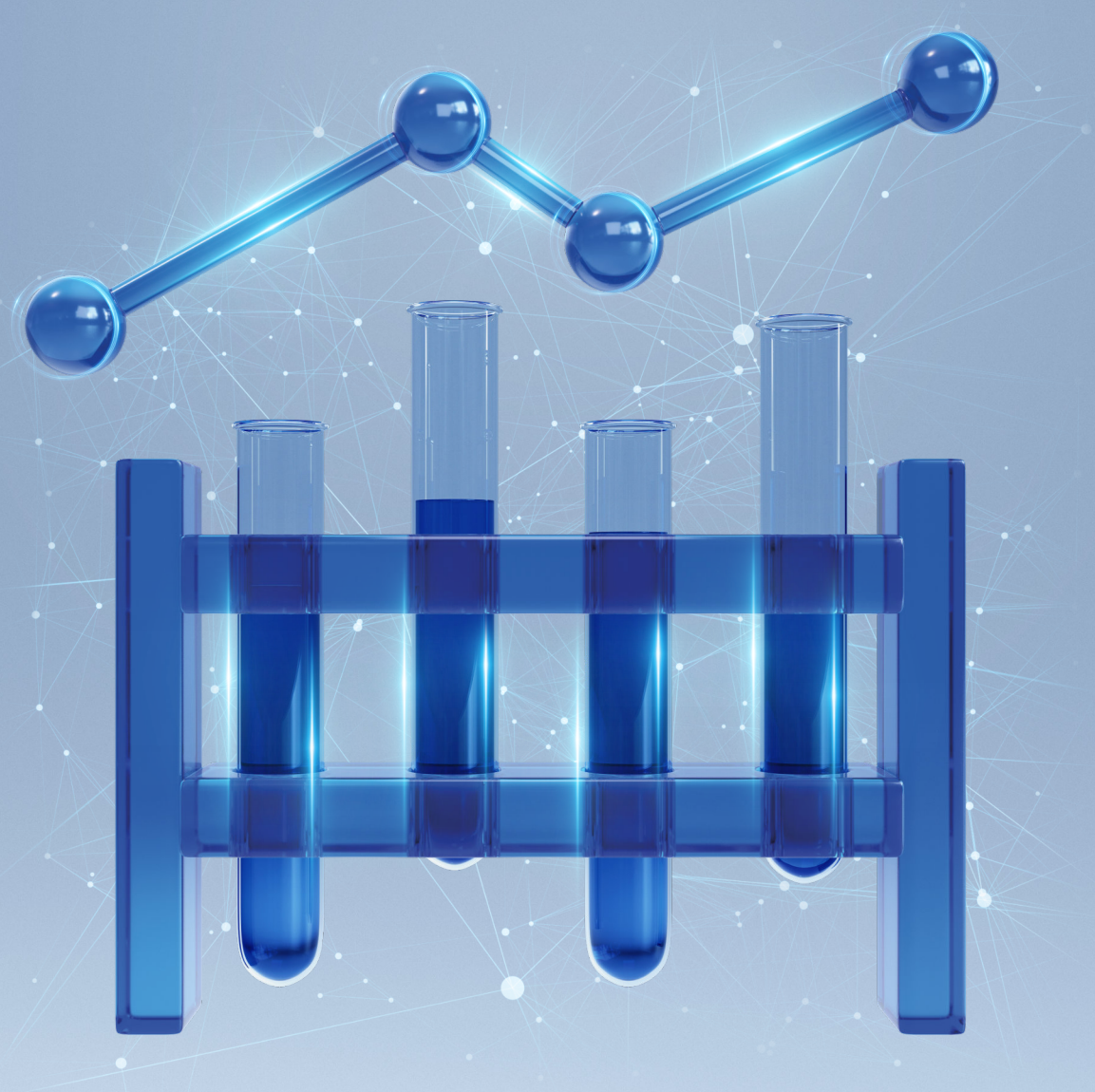
CATAPULT
Medicines Discovery



Data Access
Quick Guide to

ClinicalStudy
DataRequest.com

April 2020

ClinicalStudyDataRequest.com is a consortium of clinical study sponsors/funders facilitating access to patient-level data from clinical studies.

About CSDR

CSDR aims to be the researcher-preferred and trusted platform for the responsible access to high-quality, patient-level data from clinical studies.

They seek to facilitate innovative data-driven research, leading to improvements in patient care.

Current capabilities

Currently, CSDR contains over 3,000 trials, from 12 commercial sponsors / funders - plus a small number of academic research funders. These include over 520 separate terms for medical conditions, and 498 separate terms for medicine.

Clinical trial count split by trial phase:

- Phase 1 = 692
- Phase 2 = 715
- Phase 3 = 1,339
- Phase 4 = 391

There have been over 560 research proposals submitted so far. For up-to-date statistics, visit their metrics page.

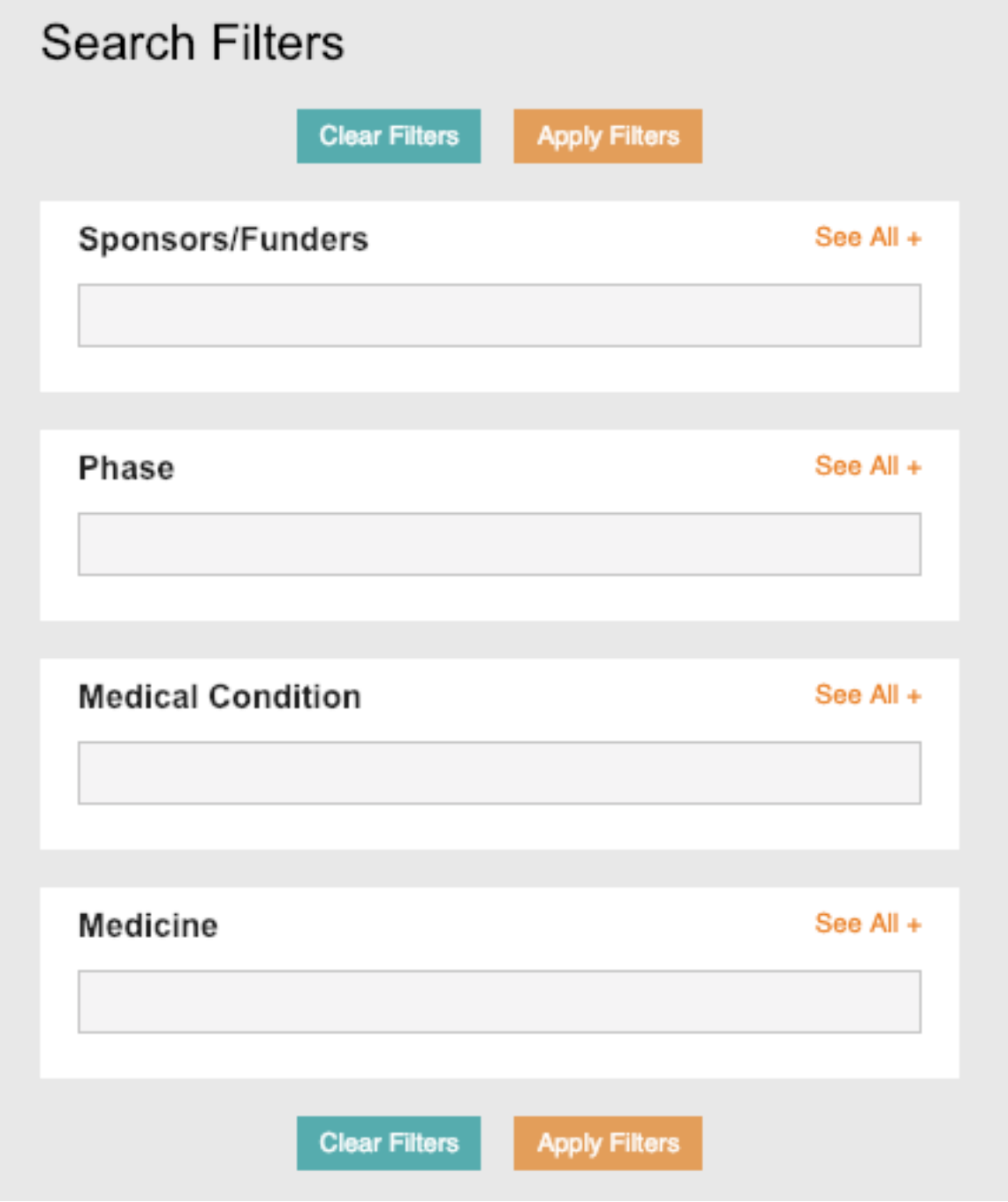
How CSDR works

ClinicalStudyDataRequest.com is a web-based application that works in most web browsers. There is no need to download or install any software to use ClinicalStudyDataRequest.com

The CSDR platform uses an application process, including independent reviews of proposals and data access, to responsibly share patient-level data. This data comes from clinical study sponsors / funders.

Requesting data

1. Search the site to see whether the study you require is already listed - searches are conducted by keyword search and can be filtered:



2. Before selecting studies, or initiating a request, you need to Login - or Create an Account.

3. *Select and View studies* to initiate a Research Proposal or ask a question about your selected studies.
4. Once you have clicked *Initiate Research Proposal*, follow the instructions within the research proposal template to complete your application through a series of free text fields
5. If the study of interest is not listed, submit an enquiry.

Review of requests

Your Research Proposals will be checked and reviewed in 3 stages:
1. By the secretariat for the Independent Review Panel (IRP) which is based at the Wellcome Trust - checks to ensure there is a qualified statistician on the research team, all fields are completed, the researcher plans to publish the analysis results.
2. By the study Sponsors / Funders – checks that proposal is compatible with study informed consent, data is available, the analysis can be conducted within the data access system, the proposal does not compete with the sponsor's publication plan, there is no conflict of interest or competitive risk.
3. By the IRP – considers the scientific rationale and relevance to medical science or patient care, the ability of the plan to meet scientific objectives, the publication plan, conflicts of interest, qualifications and experience of the research team to conduct the proposed research.

The Independent Review Panel will make one of the following decisions:

- Approval to provide access to the requested data
- Declined, with advice to re-submit the Research Proposal
- Declined Research Proposal

If no further information is needed, and depending on the number of requests received, the decision will be communicated within 90 calendar days of a Research Proposal being submitted.

You will be notified when the data for your research is anticipated to be made available.

Discover more about Review of Requests on the CSDR website >

The Data Sharing Agreement

You will be required to sign a Data Sharing Agreement (DSA) before data access can be provided. These standard documents and supporting information are available to view online.

Researchers are provided access to anonymized patient-level data and supporting documentation in a secure data access system, known as the SAS Clinical Trial Data Transparency (CTDT) system. The research project area is not accessed by Sponsors or other third parties unless Researchers request

support. A range of pre-installed statistical software is made available within the SAS research environment.

Access to data is provided for a 12-month period. Sponsors may extend access when justified for up to 24 months.

Is public disclosure required?

Yes, public disclosure of your research is required, and details of your research will be published on the CSDR website. You can find details on their Access to Data webpage.

The Data Sharing Agreement requires disclosure of the results of the analysis, in a scientific journal. If, for any reason, your analysis cannot be disclosed in a manner consistent with the publication plan, you must provide the following, in an open access journal, or on a publishing platform with a link provided on the CSDR website:

- A summary of any activity you have performed
- Any outcome of the analysis
- Reason for non-completion

All publications are to acknowledge the appropriate Sponsor(s) or Funder(s) and www.ClinicalStudyDataRequest.com as sources of data.

Find out more about ClinicalStudyDataRequest.com at their website >