Dear TraIT OpenClinica user,

As announced early 2020, TraIT OpenClinica is being phased out and will no longer continue to provide its services as of **January 31st, 2022**. More background information on what lead to this decision can be found on the Health-RI website.

Consequently, all studies making use of TraIT OpenClinica will either need to be archived or migrated to an alternative EDC. It is always the responsibility of the study PI and the leading institute to undertake the necessary steps to ensure that their study data has either been archived or migrated within the given timeframe.

However, to support the large number of studies in making this transition, Health-RI has been in contact over the past 1.5 years with individual studies, local UMC's support offices, as well as experts in the field and EDC representatives from Castor, REDCap and LibreClinica. Based on lessons learnt and experience gathered, Health-RI has set up below overview of alternative EDC's, including a new option to migrate to LibreClinica, hosted centrally by Health-RI.

Castor/REDCap

Over the last couple of years, the availability and quality of alternative EDC tools such as Castor and REDcap have substantially improved. Consequently, large parts of the Dutch research community are already served by one of these solutions and the majority of UMC's have a site license for such tools, and in some cases even an obligation for studies to make use of Castor (UMCU) or REDcap (UMCG). An overview of local experts, contact persons & available EDC tool site licenses can be found below (contact persons).

Health-RI's initial recommendation was therefore for ongoing studies to make use of available site licences and local expertise at their institute, and to migrate either to Castor or REDcap. UMCG made clear that all clinical studies led by UMCG are by default required to make use of REDcap and that all studies led by UMCG still in OpenClinica will be migrated to REDcap where necessary and useful. All other UMCs have site licenses for Castor and after having consulted several experts with experience in migrating studies (particularly large and complex studies) from OpenClinica to Castor, we have learned that this may not be the ideal solution for every study for reasons shared below.

Castor

Based on experience gathered by Health-RI, collated below is an overview of pro's and con's to be taken into consideration if migrating from OpenClinica to Castor. Please always consult your local support office who can support and guide you in making the right decision for your study (see contact persons).

Pro's

- Support and expertise available at UMC local support offices
- Castor is a professional and sustainable EDC tool
- Incurred costs are reduced through available UMC site licenses (approximately 300 euro per study per year)

Con's

- Despite availability of some scripts, the migration from OpenClinica to Castor remains for the largest part a manual undertaking
- The migration is labour intensive and requires quite some expertise to make necessary adjustments (e.g. using basic functionality such as dependencies)

- The result of migrating (particularly large and complex studies) will likely lead to frustration and disappointment from study owner (e.g. inability to use standard features in Castor due to migration from OC)
- Data will need to be exported from OpenClinica and imported into Castor where everything is accepted (also errors). The only way to check what has been imported is to open each item individually.
- Migration requires a lot of work, and the result is often sub-optimal (e.g. problematic migration of OC audit logs)

In summary: Health-RI would advise a migration to Castor if study structure is not too complex, can be set-up 'newly' in Castor, or if invested effort is worth it because study will run for years to come in Castor

- Costs: Medium (approx. 300 euro per study per year)
- Effort: High (labour intensive & expertise required)
- Result: Low - Poor (unless study structure is simple or set-up 'newly' in Castor)

Libre Clinica

The LibreClinica project was founded in 2019 to work on an open-source electronic data capture (EDC) system for clinical trials based on the OpenClinica® (OC) 3 community addition. Not only is it possible to migrate the complete OpenClinica study structure, data, and audit trail; but the updated components of LibreClinica makes it more sustainable and minimizes potential future security risks when compared to the current open-source version of OpenClinica.

Given that a migration from TraIT OpenClinica to Castor will not be optimal for several ongoing studies, as well as a few to REDcap, **Health-RI would like to offer the following alternative solution, namely a migration from TraIT OpenClinica to LibreClinica on a centrally hosted server**.

A central server will be set-up and hosted by Health-RI for TraIT OpenClinica studies that cannot migrate to Castor or REDcap and therefore need an alternative EDC until their study ends. This service is for migration purposes only and will therefore not be provided as a service for new clinical studies. This service will be offered at a cost, to be paid by the study requesting a migration to LibreClinica. The costs include support and assistance for the migration, as well as hosting and maintenance costs. The service will only be available until the finalization of the last study, preferably until no longer than end of 2023.

Costs: 300 euro per study per year

Service provided by Health-RI:

- The Health-RI LibreClinica service is for ongoing TraIT OpenClinica studies only
- Service is provided at cost until the study ends, preferably no later than end of 2023
- Cost includes study migration & support, server hosting & maintenance
- No archiving of studies
- No new clinical studies
- No sandbox environment

Requirements:

- Study currently makes use of TraIT OpenClinica and continues beyond January 31st, 2022

- Study has already contacted local support office for advice regarding alternative EDC's offered at their institution (see contact persons)
- Castor or REDcap is not a suitable option, including low ROI of migration to other tools
- Study must agree to cover costs for LibreClinica service until the study ends
- A request to migrate to LibreClinica must be made no later than **September 30th, 2021** via email to the Health-RI ServiceDesk (requests received after this date will not be processed) using attached 'procedure template for studies'.
- Study gives Health-RI permission to undertake migration to LibreClinica (available November 8th, 2021)
- Study must adhere to all timelines given by Health-RI (see below)

Timeline LibreClinica:

2021						2023
30/09	1/10 - 10-10	29/10	5/11 - 7/11	08/11	08/11 - 31/12	31/12
Study Requests LibreClinica	Test migration OC->LC	Deadline PI quality asses.	Final migration OC → LC	LibreClinica available	Payment	LibreClinica support ends
Study must request migration to LibreClinica using attached 'procedure template for studies'	A test migration is undertaken by **Health-RI** Study can continue to use OC during this time	**Study** completes data check in LibreClinica and sends approval to Health-RI ServiceDesk	Final migration of study by **Health-RI** No changes possible in OpenClinica during this time	**Study** can make use of LibreClinica	**Study** must complete payment of billing for LibreClinica service for 2022	**Studies** should no longer be ongoing

Responsibilities per step in **bold**

Contact persons: overview of local support offices & institutional EDC licenses

Institution	EDC	Site License	Central Support Office Contact
Non-UMC	-	Check availability Castor site license: https://www.castoredc.com/pricing/	Health-RI ServiceDesk servicedesk@health-ri.nl
AMC/VU	Castor	Yes	Data Management Helpdesk rdm@amsterdamumc.nl
ErasmusMC	Castor	Yes	Upon request from servicedesk@health-ri.nl
LUMC	Castor	Yes	Advanced Data Management adm@lumc.nl
Maastricht UMC+ MEMIC CTCM	Castor	Yes	Upon request from servicedesk@health-ri.nl
NKI	Castor	Yes	Upon request from servicedesk@health-ri.nl
RadboudMC	Castor	Yes	Upon request from servicedesk@health-ri.nl
UMCG	REDcap (mandatory)	Yes	Upon request from servicedesk@health-ri.nl
UMC Utrecht	Castor (mandatory)	Yes	Upon request from servicedesk@health-ri.nl