



Are you planning
to conduct
clinical research
with humans
in the near future?

Then please note
that the procedure for submitting
clinical research with humans
(both WMO and non-WMO studies)
will change.

On 3 February 2025, the CCMO will take
the new **Research Portal** into operation.
As a result, much will also change in the
way of registration and submission.

In this sheet, we set out the most
important **changes per type**
of research for you.

Central Committee on Research Involving Human Subjects



WMO/Embryo Act/MDR/IVDR

WHAT	PRESENT	IN FUTURE
System access	Log in with username and password, group accounts possible in ToetsingOnline	Personal accounts with two factor authentication in Research Portal, possible to authorize others to access files
Registration of studies	Registration of studies in ToetsingOnline	Registration of studies in Research Portal
File number	Number made up as follows: NLserial number.MREC code.year	File number will be NL-xxxxxx
Standard research file	Standard research file and code as stated on www.ccmo.nl	Minor changes in document codes in standard research files. New standard research file will be published on www.ccmo.nl in due course
Submitting research files	Submitting research files including documents at review committee (accredited MREC or CCMO) by email or other systems like ResearchManager or PaNaMa	Submitting research files including documents to review committee (accredited MREC or CCMO) in Research Portal
Questions review committee	Submitting answers to questions by review committee (MREC or CCMO) by email or other systems like ResearchManager or PaNaMa	Submitting answers to questions, amending documents, adding new documents in Research Portal
Appeals and objections	Submitting by email	Submitting in Research Portal
Objections against disclosure	Submitting objections against disclosure (core data or study results) by email	Submitting objections against disclosure (core data or study results) by email
Reminder emails	Not applicable	Reminder emails for amending data, such as recruitment status and start date in Research Portal
Publication	Not applicable	Studies published in OMON. Thus ICMJE-requirements are met. Also, potential research participants may search for and find studies in OMON
Information during and after the study	Submitting progress reports, start date, temporary stop, (premature) end of study and results through ToetsingOnline, email or external systems like ResearchManager of PaNaMa	Submitting progress reports, SAE's, recruitment status, start date, end of study, results in Research Portal
Studies in ToetsingOnline	Ongoing and finished studies can be found in ToetsingOnline	Ongoing studies (with the exception of studies in transition to CTR) will be migrated to Research Portal, for details visit www.ccmo.nl

Non-WMO studies falling under the DCRF Assessment Framework

(initiated and/or financed by pharmaceutical companies)



WHAT	PRESENT	IN FUTURE
System access	Not applicable	Personal accounts with two factor authentication in Research Portal
New submissions, amendments, notification end of study	All submissions to be made through emails	All submissions to be made in Research Portal
Questions nWMO Advisory committee and submitter's response	Submitter receives questions from Advisory committee by email and responds to these by email	Submitter receives questions from Advisory committee as before, responses (answers to queries, amended documents and new documents) to be submitted in Research Portal
Research number	The number is made up as follows: NWMOyear.month.serialnumber for primary submission, number first submission+A+date submission amendment as YY.MM.DD for amendment	Number will be NL-xxxxxx
Standard research file	Standard research file and document code as stated on www.nwmostudies.nl	Minor changes in document code in the new standard research file. The new standard research file will in due course be published on www.nwmostudies.nl
Reminder emails	Not applicable	Submitter receives reminder emails to amend data in Research Portal, such as recruitment status and start date
Publication	Not applicable	Studies published in OMON. Thus ICMJE-requirements are met. Also, potential research participants may search for and find studies in OMON.
Additional information	Not applicable	Keeping the status of the study up to date (recruitment status, start date, etc.), submitting results with regard to public register OMON

Other non WMO studies

(facultative registration in a research register)

WHAT	PRESENT	IN FUTURE
System access	Not applicable	Personal accounts with two factor authentication in Research Portal
New submission	Registering new studies not possible	Possible to register studies in OMON. Studies are published in OMON. Thus ICMJE-requirements are met. Also, potential research participants may search for and find studies in OMON
Amending study data	Amending data of studies originally registered in NTR by completing the form 'Update of NTR registration' on www.onderzoekmetmensen.nl	Amending data of studies originally registered in NTR to be submitted by an amendment in Research Portal
Reminder emails	Not applicable	Submitter receives reminder emails to amend data in Research Portal, such as recruitment status and start date.



For more information on the transition to the new Research Portal and the new procedures, please consult:

www.ccmo.nl