

Open Consortium for Decentralized Medical Artificial Intelligence
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## **Deliverable D2.6**

# STUDY INITITIATION PACKAGE

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#### **EXECUTIVE SUMMARY**

ODELIA has been registered as a clinical trial and the process of collecting the approval of the respective ethical committees has been started at every data-contributing site.

#### INTRODUCTION

In this deliverable we describe the current status of the registration of ODELIA as a whole as well as the current status of each data-providing partner's stance on the ethical agreement needed to conduct the study.

#### **CLINICAL TRIAL REGISTRATION FOR ODELIA**

ODELIA has been registered at ClinicalTrials.gov with the identifier NCT05698056.

#### APPROVAL OF LOCAL ETHICS COMMITTEES

- University Hospital Aachen (UKA): The study has been approved by the ethics committee.
- Vall d'Hebron Institute of Oncology (VIHO): Approval for a similar project exists, currently VHIO is applying for an updated version
- University Hospital Zurich (USZ): The study has been approved by the ethics committee.
- University Medical Center Utrecht (UMC): Application has been submitted to the ethics committee and is currently pending approval.
- University of Cambridge (CAM): Application has been submitted to the ethic's committee and is currently pending approval.
- MITERA: The study has been approved by the ethic's committee.
- Radboud university medical center (RUMC): Approval for a similar project exists, currently RUMC is applying for an updated version
- RIBERA: Application has been submitted to the ethic's committee and is currently pending approval.

Note, that partners will not perform actions that might require approval or deliver data until approval by the local ethics committee has been granted. Preparatory work will however already commence.

#### CONCLUSION

At the current point in time, we foresee no roadblocks to conduct ODELIA as planned. All necessary steps have been initiated.



