ORDECA – ORGANOID DRUG SCREENING FOR ENDOMETRIAL CANCER IDENTIFYING NOVEL DRUGS AND BIOMARKERS FOR TREATING ENDOMETRIAL CANCER USING A HIGH-THROUGHPUT PATIENT-DERIVED ORGANOID DRUG DISCOVERY AND SCREENING PLATFORM

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Creator: Emma Laporte

Affiliation: KU Leuven (KUL)

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Project abstract:

Cancer of the womb's inner lining (i.e. endometrial cancer, EC) is the most common gynecological malignancy and third cause of cancer-related death in women. Indeed, current treatments, typically surgical tumor removal and radio-/chemotherapy, remain inadequate in a high number of cases, frequently followed by recurrence of the cancer. Indeed, effective therapy of EC represents a high unmet clinical need in the women's health domain. We established organoid models from patient-derived EC which closely reproduce the original tumors, thus representing very powerful preclinical models. Importantly, organoids are robustly expandable and efficiently amenable to drug discovery and efficacy screens. In our project, we will identify novel and effective drugs to tackle EC by applying an automated high-throughput organoid drug screening platform. Moreover, the associated deep omics analyses will uncover response-predictive biomarkers, direly needed to appropriately stratify EC patients toward optimal (personalized) treatment.

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Research Data Summary

List and describe all datasets or research materials that you plan to generate/collect or reuse during your research project. For each dataset or data type (observational, experimental etc.), provide a short name & description (sufficient for yourself to know what data it is about), indicate whether the data are newly generated/collected or reused, digital or physical, also indicate the type of the data (the kind of content), its technical format (file extension), and an estimate of the upper limit of the volume of the data.

Dataset name / ID	Description	New or reuse	Digital or Physical data	Data Type	File format	Data volume	Physical volume
		Indicate: ***N****(ew data) or* ***E****(xisting data)*	Indicate: **D**(igital) or **P**(hysical)	Indicate: **A**udiovisual **I**mages **S**ound **N**umerical **T**extual **M**odel **SO**ftware Other (specify)		Indicate: <1GB <100GB <1TB <5TB >5TB NA	
Endometrial cancer biopsies	Biopsies are obtained via UZ Leuven (under ethical approval).	N	P	NA	NA	NA	<200 samples
PDOX mouse models	Essential for in vivo validation of the most interesting compounds for their potential to treat endometrial cancer	N	P	NA	NA	NA	90 mice
Cryopreserved samples and organoids	Cyropreservation in biobank of primary samples and organoids.	E	P	NA	NA	NA	<200 samples
Paraformaldehyde (PFA)-fixed patient endometrial biopsies and organoids	Organoids and fixed samples are obtained as published in PMID: 28442471 and stored in designated storage spaces.	N	P	NA	NA	NA	<500 samples
RNA from biopsies, organoids	RNA samples are obtained from primary tissue as well as from organoids at multiple passages. (Storted at -80°C).	N	P	NA	NA	NA	<500 samples
cDNA from biopsies, organoids	cDNA samples are obtained from primary tissue and organoids (Storted at -20°C).	N	P	NA	NA	NA	<500 samples
Lab book	Notes on experiments, observations in the lab	N	D/P	I, N, T	.ONE	<4GB	NA
PCR results	gel electrophoresis (gel image) obtained via Image Lab software	N	D	I	.tiff	<1GB	NA
Light epifluorescence and confocal images + image analyses data	Images and derived quantitative data from (sections) of organoids and primary tissue/biopsy.	N	D	I, N	.lif, .lsm, .tiff .xlsx	<5TB	NA
RNA/DNA concentration/quality	Information obtained after RNA extraction via measurement with Nanodrop	N	D	N	.xlsx	<100MB	NA
RT-qPCR data/graphs	Data/graphs created via QuantStudio Real Time PCR software	N	D	N	.xlsx, .eds, .pzfx	<100GB	NA
Sequencing data	(sc)RNAseq NGS	E/N	D	N	.xlsx, .rds, .fastq, .fasta, .pdf	<1TB	NA
Experimental analysis and manuscripts	Analysis of obtained data summarized in presentations/excel/Graphpad files	N	D	I, N, T	.xlsx, .docs, .ppt, .prism	<1GB	NA
Biopsy and organoid biobank database	Database on storage of samples in biobank	E/N	D	N, T	.xlsx	<100MB	NA

If you reuse existing data, please specify the source, preferably by using a persistent identifier (e.g. DOI, Handle, URL etc.) per dataset or data type:

Use of already obtained endometrial biopsies of healthy women and patients with endometrial cancer in our lab. (DOI: 1038/s41556-019-0360-z)

Use of published scRNA-seq datasets of endometrial biopsies/organoids from healthy women and patients with endometrial cancer. (DOI: 1038/s41556-019-0360-z)

Are there any ethical issues concerning the creation and/or use of the data (e.g. experiments on humans or animals, dual use)? If so, refer to specific datasets or data types when appropriate and provide the relevant ethical approval number.

- Yes, human subject data (Provide SMEC or EC approval number below)
- Yes, animal data (Provide ECD reference number below)

For human:
Patients' relevant clinical data will be retrieved from 'UZ Leuven clinical work station'. Patients' name and identity data will be kept in a separate encrypted database
(access authorization for PI and 1 delegated researcher, with audit trail). Permission for healthy and diseased endometrium research has been obtained from the Ethical Commission Research UZ/KU Leuven (S59006, S59177, S62765 and S68096)
For mice: We have two approved breeding projects (000/(GS1/GS2)Breeding-Vankelecom and 000/(GS3) Breeding Hugo Vankelecom) and we will apply for an expiremental project license from the ECD in year 2 of the project, so we can start with the mice experiments in year 3.

Will you process personal data? If so, please refer to specific datasets or data types when appropriate and provide the KU Leuven or UZ Leuven privacy register number (G or S number).

- Yes (Provide PRET G-number or EC S-number below)

The personal data has been rendered pseudonymised and is registered in the KU Leuven's internal processing of personal data register. This way the individual is no
longer identifiable for us, but can be re-identified if necessary (through the doctor). We will only work with patient information including age, ProMisE class, histotype/stage/grade, treatment etc.

Approved under ethical dossier: S59177.

Does your work have potential for commercial valorization (e.g. tech transfer, for example spin-offs, commercial exploitation, …)? If so, please comment per dataset or data type where appropriate.

- Yes

We will perform high-throughput drug screens on the patient derived organoids, enabling for the discovery and development of innovative medicines to treat endometrial cancer. The specific exploitation objective is to spin-off endometrial cancer assets in an innovative women's health therapeutic company.

Do existing 3rd party agreements restrict exploitation or dissemination of the data you (re)use (e.g. Material or Data transfer agreements, Research collaboration agreements)? If so, please explain in the comment section to what data they relate and what restrictions are in place.

- No

Are there any other legal issues, such as intellectual property rights and ownership, to be managed related to the data you (re)use? If so, please explain in the comment section to what data they relate and which restrictions will be asserted.

- No

Documentation and Metadata

Clearly describe what approach will be followed to capture the accompanying information necessary to keep data understandable and usable, for yourself and others, now and in the future (e.g. in terms of documentation levels and types required, procedures used, Electronic Lab Notebooks, README.txt files, codebook.tsv etc. where this information is recorded).

- Documentation of the mice: in an excel file the following information will be noted for every mouse: cage number, date of birth, gender, derived from which breeding
couple, genotype, sacrifice date, used in which experiment.
- Daily lab activities are recorded in detail in the online lab book (OneNote).
- For documentation of microscopy images (of organoid cultures) the following information will be noted: date, experimental condition, passage of organoid culture,
amount of days in culture, magnification used. Images will be saved on the shared drive of the lab and KU Leuven OneDrive in a designated folder of the particular
experiment. Within the experiment folder, additional folders are labeled in a clearly structured way (according to different experimental conditions or different timepoints
within the experiment). The setup of an experiment is written down in the lab book. A meta data file, generated by the microscope program, is saved automatically
together with the image.
- For RNA and cDNA concentration and quality measurements using Nanodrop: 260/230 and 260/280 ratios (quality measure) and concentrations are written down in lab
book and later transferred manually to an excel file where all previous RNA/cDNA measurements are stored. Date of measurement together with name of the sample is
included.
- For qPCR data: excel file containing sample setup, raw data, results, melt curve data are given the name: "date, qPCR_experiment name". The qPCR data is saved in a
"qPCR folder" within the folder of the specific experiment, together with the template of the particular qPCR reaction. Name of the template file: "date, qPCR_experiment
name_layout". Graphs from the data are made using Graphpad Prism (.pzfx file). File is named: "date, Graphs_expriment name", and saved in the same folder.
- Methodology and protocols for RNA extraction, cDNA preparation, immuno-histochemistry stainings, organoid culture, medium preparation... are all included in the lab
book and stored on KU Leuven OneDrive in a designated folder.

Will a metadata standard be used to make it easier to find and reuse the data?
If so, please specify which metadata standard will be used.

If not, please specify which metadata will be created to make the data easier to find and reuse.

- No

Currently, metadata standards are not implemented in the research group. Metadata are generated during microscopy, RT-qPCR analyses and from sequencing data.
In general, to make the data easy to find, a personal folder on the shared drive of the lab and OneDrive is made and is further subdivided a clearly structured way (e.g.
specific folders for different experiments). In the lab book a description of every experiment can be found including all the experimental conditions

Data Storage & Back-up during the Research Project

Where will the data be stored?

- Large Volume Storage
- Shared network drive (J-drive)
- Personal network drive (I-drive)
- OneDrive (KU Leuven)
- Sharepoint online

How will the data be backed up?

- Standard back-up provided by KU Leuven ICTS for my storage solution

Is there currently sufficient storage & backup capacity during the project?

If no or insufficient storage or backup capacities are available, explain how this will be taken care of.

- Yes

How will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

Access to the computer, shared drive of the lab and KU Leuven OneDrive are secured by a 2-step authentication process with personal log-in (personal u-number and password) and
activation of the multifactor authenticator app provided by the KU Leuven.
Physical data is securely stored in the lab and offices that are only accessible through a badge system.

What are the expected costs for data storage and backup during the research project? How will these costs be covered?

As long as the data does not exceed the 2 TB of storage of the KU Leuven OneDrive, no additional costs for data preservation are expected. If the storage capacity exceeds 2 TB, KU Leuven provides a large volume storage for research data in a cost-efficient manner: 104,42 euro/TB/year (to be purchased in blocks of 5 TB)

Data Preservation after the end of the Research Project

Which data will be retained for 10 years (or longer, in agreement with other retention policies that are applicable) after the end of the project?

In case some data cannot be preserved, clearly state the reasons for this (e.g. legal or contractual restrictions, storage/budget issues, institutional policies...).

- All data will be preserved for 10 years according to KU Leuven RDM policy

Where will these data be archived (stored and curated for the long-term)?

- Shared network drive (J-drive)

What are the expected costs for data preservation during the expected retention period? How will these costs be covered?

If the storage capacity exceeds 2 TB, KU Leuven provides a large volume storage for research data in a cost-efficient manner: 104,42 euro/TB/year (to be purchased in blocks of 5 TB).

Data Sharing and Reuse

Will the data (or part of the data) be made available for reuse after/during the project?
Please explain per dataset or data type which data will be made available.

- Yes, as restricted data (upon approval, or institutional access only)

Reason for restricted access: Intellectual property rights. We expect to use the data for industrial/commercial exploitation and potential patents. Before publishing the data we will check with LRD if we can publish the data openly before doing so.
Internally (within the research group) the data will be openly shared and can be reused.

If access is restricted, please specify who will be able to access the data and under what conditions.

Reason for restricted access: Intellectual property rights. We expect to use the data for industrial/commercial exploitation and potential patents. Before sharing, we will check with LRD if we can publish the data openly before doing so.
Data can potentially be shared with other involved parties under MTA/CDA and collaboration agreements. For data sharing agreements (advise and templates), we will contact LRD.

Are there any factors that restrict or prevent the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions)?

Please explain per dataset or data type where appropriate.

- No

Where will the data be made available?

If already known, please provide a repository per dataset or data type.

- KU Leuven RDR (Research Data Repository)

When will the data be made available?

- Other (specify below)

We expect to use the data for industrial/commercial exploitation and potential patents. Therefore data sharing will be postponed to protect IP during patent application.

Which data usage licenses are you going to provide?

If none, please explain why.

- Data Transfer Agreement (restricted data)

Do you intend to add a persistent identifier (PID) to your dataset(s), e.g. a DOI or accession number? If already available, please provide it here.

- Yes, a PID will be added upon deposit in a data repository

What are the expected costs for data sharing? How will these costs be covered?

There are currently no expected costs for data sharing.

Responsibilities

Who will manage data documentation and metadata during the research project?

Designated postdoctoral researcher and lab technician.

Who will manage data storage and backup during the research project?

Designated postdoctoral researcher and lab technician.

Who will manage data preservation and sharing?

The PI, prof. Dr. Hugo Vankelecom

Who will update and implement this DMP?

Designated postdoctoral researcher during the research project. Upon completion of the project, the PI prof. Dr. Hugo Vankelecom will take over.
The PI, prof. Dr. Hugo
Vankelecom, bears the end responsibility of updating & implementing this DMP.