DMP - C3 microBAT

ADMIN DETAILS

Grant number: C3/21/014

Project Name: microBAT: MIcrofluidics Cartridge for RemOte Biofluids AcquisiTion

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Description: Remote (self) sampling is not widely adopted in clinical practice as current solutions (e.g. dried blood spot (DBS) cards) do not provide reliable and standardized samples. Moreover, they are mostly focused on blood, thus not exploiting other invaluable biofluids (e.g. saliva, sweat, interstitial fluids), while on-spot processing of the sample is not possible, which limits the downstream analyses. The aim of the microBAT project is to develop an innovative platform for remote microsampling of biofluids in a standardized and accurate manner with unprecedented on-chip sample processing capability. This will be achieved by further building on our microfluidic technology, recently validated in the field as a volumetric DBS cartridge. This versatile sampling platform will be validated in clinical settings (e.g. general practitioner's office) in the context of therapeutic drug monitoring, human biomonitoring and infectious diseases population screening, using capillary blood and saliva, the latter being a noninvasive but highly relevant emerging sample. The project will be realized by an interdisciplinary consortium consisting of technological, clinical and valorization experts. The data created are design files, fabrication protocols, and measurement procedures. In addition, extensive measurement data (e.g. video recordings, microscopy images, analytical results) are being collected.

Institution: KU Leuven

1. GENERAL INFORMATION

Name of the project lead (PI)

- Jeroen Lammertyn, Francesco Dal Dosso, Jan Verbakel

C3 Project number & title

- C3/21/014 - microBAT – MIcrofluidics Cartridge for RemOte Biofluids AcquisiTion

2. DATA DESCRIPTION

2.1. Will you generate/collect new data and/or make use of existing data?

- Generate new data

2.2. What data will you collect, generate or reuse? Describe the origin, type and format of the data (per dataset) and its (estimated) volume. This may be easiest in a numbered list or table and per objective of the project.

- WP1. Microfluidic toolbox for biofluids sampling and processing
    - Design of microfluidic chips: CAD files (e.g. .svg). Expected volumes = 2 GB
    - Visualization of microfluidic chip operations during design optimization: video recordings with camera/webcam (e.g. .mp4, .avi). Expected volumes = 500 GB
    - Visualization and quantification of the number of red blood cells in the separated plasma samples: Microscopic images (.tiff, .JPEG). Expected volume = 25 GB
    - Visualization of mixing behavior and efficiency: video recordings with camera/webcam/fluorescence microscope (e.g. .mp4, .avi), which will be processed in Matlab software (.m). Expected volume = 50 GB
    - Collection and processing of primary numerical data (spectrophotometer) for the characterization of the dilution accuracy are processed in standard software (MS Excel) and electronic lab books (eLABJournal, Bio-ITech). Expected volume = 1 GB
- WP2: Development and laboratory validation of microBAT sampling cartridges
    - Design of microfluidic chips: CAD files (e.g. .svg). Expected volumes = 2 GB
    - Visualization of microfluidic chip operations during design optimization: video recordings with camera/webcam (e.g. .mp4, .avi). Expected volumes = 100 GB
    - Collection and processing of primary numerical data (ELISA, COBAS800, LC-MS and RT-PCR) are performed using standard software (MS Excel) and electronic lab books (eLABJournal, Bio-ITech). Expected volume = 5 GB
- WP3: Innovative fabrication solutions towards microBAT cartridges industrialization
    - Collection and processing of primary numerical data (.csv) of accelerated liquid storage experiments in standard software (MS Excel) and electronic lab books (eLABJournal, Bio-ITech). Expected volume 500 MB
    - Design of microfluidic chips: CAD files (e.g. .svg, .dwg) for the R2R UV-nanoimprint manufacturing process. Expected volumes = 1 GB
    - Evaluation of device quality and performance of the R2R fabricated demonstrator devices
        - Assessing channel resolution and alignment: microscopic images (.tif). Expected volume = 5 GB
        - Visualization of microfluidic chip operations: video recordings with webcam/Camera (e.g. .mp4, .avi). Expected volume = 10 GB
- WP4: Field validation of microBAT cartridges in clinical settings
    - Collection of primary numerical data for the validation study of the microBAT$_{TDM}$ (ELISA, and COBAS800) and microBAT$_{ID}$ (RT-PCR) demonstrators are performed using standard software (MS Excel) and electronic lab books (eLABJournal, Bio-ITech).
    - Data from questionnaires are collected with dedicated software (e.g. Castor, KUL-Qualtrics). Expected volume = 500 MB

    - The collected data will be processed and analyzed with statistical software JMP Pro, RStudio and Matlab. Expected volume = 1 GB
- WP5: Project management and valorization activities
    - Observational data: written down in electronic lab notebook (eLABJournal, Bio-ITech)
    - Consortium meetings: update presentations, meeting reports (e.g. .pptx, .docx). Expected volumes = 10 GB
    - Scientific publications and doctoral dissertations (e.g. .docx and .pdf). Expected volumes = 10 GB
    - Administrative documents: project reports, financial reports (e.g. .docx and .xlxs), dissemination materials (e.g. .docx, .pptx, .png, .jpg). Expected volumes = < 1 GB

3. ETHICAL AND LEGAL ISSUES

3.1. Will you use personal data? If so, shortly describe the kind of personal data you will use. Add the reference to the file in KU Leuven's Record of Processing Activities. Be aware that registering the fact that you process personal data is a legal obligation.

- Yes, participants involved in the study will be asked to fill in a questionnaire to assess the user experience on a 5-point Likert scale of the proposed sampling devices together with general information (e.g. name, age, gender).

3.2. 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, add the reference to the formal approval by the relevant ethical review committee(s).

- Yes.

  No ethical clearance is required to start the project, but the necessary approval will be requested at the Ethical Review Board of UZ/KU Leuven and UZ/KU Leuven Biobank before the start of the relevant work packages. In particular, for the laboratory validation of the MicroBAT cartridges in WP2 (6 months after the start of the project) there will be worked with human whole blood. The biofluid will be collected from healthy volunteers, after obtaining informed consent. Furthermore, the clinical validation of the MicroBAT cartridges in WP4 (2 years after the start of the project) will involve biofluid collection from patients after obtaining informed consent and therefore will require ethical approval. During this clinical study also personal data will be collected through questionnaires filled in by the participating GPs in which the user experience of the devices will be assessed.

3.3. Does your research possibly result in research data with potential for tech transfer and valorisation? Will IP restrictions be claimed for the data you created? If so, for what data and which restrictions will be asserted?

- Yes

  We do expect new IP generation in the field of microfluidics for both point-of-care microsampling and sample processing applications (e.g. reagent mixing and dilution, plasma separation). Moreover, novel microfabrication approaches and methods are expected to be developed in the

context of R2R UV-nanoimprint manufacturing process (Joanneum Research) of the cartridges and localized molecule deposition using atmospheric plasma deposition (MPG). When there is concrete potential for tech transfer, the IP related to these research data will be protected, with the support of KU Leuven LRD and the IOF manager supporting this project (Dr. F. Dal Dosso).

3.4. Do existing 3rd party agreements restrict dissemination or exploitation of the data you (re)use? If so, to what data do they relate and what restrictions regarding reuse and sharing are in place?

- There are no 3rd party agreements in place regarding this project.

4. DOCUMENTATION AND METADATA

4.1. What documentation will be provided to enable understanding and reuse of the data collected/generated in this project?

- Protocols, the research progress and clear descriptions of obtained data, what they represent and how they were generated, will be collected in the Biosensors group in an electronic notebook (eLABJournal, Bio-ITech). Here, folders will be provided for all subtasks of the project. In each folder, a new file will be made for each experiment, named with the date and subject, and including information on the responsible person (i.e., the person who created the file) as well as version tracking. Each experimental file will contain a section on the objective, protocol, results (a description of results and observations rather than all raw and analysed data) and conclusions. For each experiment, all raw and analysed data files will be stored in a folder on the shared server, using the same hierarchical folder structure as the electronic lab notebook. By using the same structure on the server and in the electronic lab notebook, contextual information on the experimentally obtained data can be easily searched and used by a secondary analyst via the electronic notebook.
- Most important (raw)data which lead to publications (e.g. conference proceedings, journal paper) and/or to patents filings, will be stored on the shared folder created on the shared drive (J:\SET-MEBIOS-BIOSENSORS-PROJ-DI0443\C3 microBAT). This folder is open to all the consortium members and is secured and backed-up by the ICTS service of KU Leuven. This folder contains also all the administrative items (e.g. project proposal, project reports, update presentations, contracts)

4.2. Will a metadata standard be used? If so, describe in detail which standard will be used. If not, state in detail which metadata will be created to make the data easy/easier to find and reuse.

- Being a highly interdisciplinary project, it is not possible to use a standard metadata system.
- The Biosensors group will use the electronic lab notebook in which a number of predetermined topics have to be described for each experiment (Objective, protocol, results, and conclusion). The electronic lab notebook facilitates searching for particular metadata through a search engine. By mimicking the folder structure of the electronic lab notebook in the server-based folder with the experimental data, linking of the metadata to the actual data will be facilitated.

- The electronic lab book software will also be used to manage the patient sample inventory (coded label, position, date) and track samples in and out of the fridges and freezers.
- For each peer-reviewed article, a separate folder will be made on the server, containing the latest word version and all raw and processed data used in the article. In addition, a separate file will be made in the electronic lab notebook for each article, containing clickable links to all metadata files of data that were used in that particular article, to facilitate tracing back of protocols, results and conclusions.

5. DATA STORAGE AND BACKUP DURING THE C3 PROJECT

5.1. Where will the data be stored?

- The time-stamped digital data will be stored in an already created project folder on the shared drive (J:) of KU Leuven. The time-stamped digital metadata will be stored on the server of the electronic labbook (eLABJournal, Bio-ITech), and .pdf exports will be made on a weekly basis to be saved on the shared drive (J:). The folder is open for the members participating in this KU Leuven C3 project and is secured and backed-up by the ICTS service of KU Leuven. Copies can be made and kept on personal devices.

5.2. How will the data be backed up?

- The digital data will be stored on the university's central servers with automatic daily back-up procedures.

5.3. Is there currently sufficient storage & backup capacity during the project? If yes, specify concisely. If no or insufficient storage or backup capacities are available, then explain how this will be taken care of.

- Yes
  KU Leuven provides sufficient storage and back-up capacity during and after the project. A dedicated folder will be made for the project on which the collaborators will work jointly and store data files.

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

- Type 1 server back-end storage with mirror backup for the project share folder will cost 519 Euro per Tb per year. Costs will be covered by the project consumables budget.

5.5. Data security: how will you ensure that the data are securely stored and not accessed or modified by unauthorized persons?

- The network drive for the project share folder and the large volume storage folder are secured by the ICTS service of KU Leuven with a mirror copy. Only lab members that work on the project, will have access to the shared folder. Confidential data can and will be protected with a password (available only for PI Jeroen Lammertyn). Visitors, MSc thesis students and internship students in the groups as well as other unauthorized persons will not have access to the data on the shared

folder. Data storage in the cloud will be avoided, unless for temporary use only, e.g., to transfer large files between the researchers involved in the project.

6. DATA PRESERVATION AFTER THE END OF THE C3 PROJECT

6.1. Which data will be retained for the expected 10 year period after the end of the project? If only a selection of the data can/will be preserved, clearly state why this is the case (legal or contractual restrictions, physical preservation issues, ...).

- The data to be retained during 10 years after the project's end are dissemination data (source files of publications and presentations), documentation on measurements set-ups, and the most relevant measurement data.

6.2. Where will these data be archived (= stored for the long term)?

- A distinction is made between research data and dissemination data. The research data, namely microscopy images, video recordings and measurement results, will be stored on an external hard drive after the end of the project. Dissemination data, namely files corresponding to papers and presentations, will be stored on the PI's PC, and back-upped daily on the departmental server for long term storage.

6.3. What are the expected costs for data preservation during these 10 years? How will the costs be covered?

- The volume corresponding to dissemination data is expected to be relatively low (<10 GB), and therefore can be seamlessly embedded in the PI's allocation on the departmental server. The costs (1000 EUR/year) will be covered by other on-going projects at that point in time.
- The research data will be stored on an external hard disk. As the lifetime of such external hard disk may not be adequate, the data to be preserved will be moved to a new hard disk, purchased on the budget of a follow-up project, when needed. This is adequate, as the volume of such external hard disks is expanding considerably over time.

7. DATA SHARING AND RE-USE

7.1. Are there any factors restricting or preventing the sharing of (some of) the data (e.g. as defined in an agreement with a 3rd party, legal restrictions or because of IP potential)?

- No

7.2. Which data will be made available after the end of the project?

- Relevant digital data will be published and made available after the end of the project. Data with valuable IP will be protected prior to publication. We will comply with open access regulations of KU Leuven.

7.3. Where/how will the data be made available for reuse?

- Upon request by mail
- The approach to share data is upon request by e-mail. Due to the data volume, access will then be granted to a restricted access repository.

7.4. When will the data be made available?

- Upon publication of the research results
- As soon as the research results have been published, the data can be made available to other researchers.

7.5. Who will be able to access the data and under what conditions?

- All project collaborators will be authorized to have access to all obtained digital and physical data after the project
- In case the question originates by researchers outside the consortium, the data can be made available upon e-mail request, and on condition that the users agree to give proper credit, such as co-authorship on their papers building on these data.
- Usage for commercial purposes will require obtaining a license, or equivalent arrangement.

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

- A restricted access repository can be implemented on a free tool, such as Dropbox, up to a certain volume. If this volume does not suffice, time-limited storage will be considered, thus limited to the time needed to download the data.

8. RESPONSIBILITIES

8.1. Who will be responsible for the data documentation & metadata?

- The lab technician and researchers who will work on this KUL C3 project will be responsible for the data collection, documentation and metadata. They will be trained in data management at the beginning of the project. Supervisors will manage the data storage facilities.

8.2. Who will be responsible for data storage & back up during the project?

- The lab technician and researchers who will work on this KUL C3 project will be responsible to store the data on the appropriate accommodation provided by KU Leuven. The ICTS service of KU Leuven is responsible for the back-up of the network drives at KU Leuven. The folders will be managed by the supervisors.

8.3. Who will be responsible for ensuring data preservation and sharing?

- The PIs of this project will be responsible for the data preservation and eventual reuse of obtained data.

8.4. Who bears the end responsibility for updating & implementing this DMP?

- The PIs bear the end responsibility of updating and implementing the DMP.