EurOPDX Research Infrastructure Trans-national Access (TA) Program

Guide for applicants

Version 3.0

Open Call opens – 14th February 2020

Two proposal submission cut-off dates – 31st March & 16th June 2020

www.europdx.eu/europdxri-ta

Helpdesk & Proposal submission:
ta@europdx.eu

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1. Introducing the Trans-national Access program of the EurOPDX Research Infrastructure

The **EurOPDX Consortium** was established in 2013 as an initiative to promote scientific collaboration in PDX research in Europe, integrate available PDX collections and raise standards in the field (www.europdx.eu). EurOPDX is **now teaming up with other key academic and SME partners in a four-year project to build the "EurOPDX Distributed Infrastructure for Research on patient-derived Xenografts"** (EDIReX project funded under EU's H2020 research and innovation programme, grant no. 731105).

The project is building a cutting-edge and novel EurOPDX Research Infrastructure (RI) for PDX research, providing the scientific community with a **user-friendly public repository to facilitate PDX data sharing and selection of models of interest by users** (dataportal.europdx.eu/), and **opening access by 2020 to approximately 1000 PDX models from 10 different cancer types** established by EurOPDX Consortium members, for which clinical, molecular, and pharmacological annotations are currently curated. To facilitate PDX resource sharing and promote reproducibility of preclinical data, the project is developing **Standard Operating Procedures (SOPs) for PDX biobanking, quality control, and *in vivo* studies**, which will be made available on the project website (www.europdx.eu/standards). Those standards are being shared and discussed with the global PDX community in order to reach a global impact on PDX research.

The EurOPDX RI **Trans-national Access (TA) program** is meant to allow **free-of-charge remote access to PDX resource and expertise for academic and industry researchers in Europe and Worldwide**. **Three TA calls for proposals** are planned under the current grant. Two have been launched already in October 2018 and September 2019, with access now ongoing. The third call was published mid-February 2020 in the form of an Open Call with two cut-off dates. Access to models is offered through **six state-of-the-art PDX facilities or "nodes"** in the following institutions: University of Turin (Italy), Katholieke Universiteit Leuven (Belgium), Netherlands Cancer Institute (The Netherlands), University of Cambridge (UK), Institut Curie (France), and Vall d'Hebron Institute of Oncology (Spain). **Since the 2nd call in 2019, hands-on training opportunities in the nodes** are also available to users, primarily targeted at early career researchers and technical staff.

To get introduced to the EurOPDX RI, you can also watch our **video on YouTube**: https://youtu.be/qYjityqXmNg

The present "Guide for applicants" is meant to detail the different possibilities of access to PDX models currently offered by the EurOPDX RI, the application and selection procedures and the implementation of access for selected users.

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2. OPEN CALL for proposals: Types of access & Key dates

2.1 Types of access

For the ongoing Open TA Call of the EurOPDX Research Infrastructure, **three types of access to the PDX resource will be possible** through each of the six infrastructure nodes:

- **SAMPLE = shipment of frozen PDX tumour samples to selected academic laboratories**

Each user of the infrastructure will receive viable tissue aliquots from the PDX models she/he would have selected for their particular features in the public EurOPDX Data Portal (dataportal.europdx.eu). Prior to shipment, all PDX models will have been expanded, biobanked, and quality controlled (histology, identity check, health monitoring) in one of the six nodes according to the standards agreed within the EurOPDX RI (see Figure 1 below). Each model will be accompanied by a "PDX passport", a factsheet developed by the EurOPDX RI to contain all main features of a given PDX model, such as histology, strain, growth characteristics. Access also includes support/consulting to the users after shipment of models, for the handling of samples, design of *in vivo* studies etc…

The access to the SAMPLE service is **free of charge, and available for the performance of non-commercial research activities only**. However, the shipment cost of frozen vials to the user's laboratory must be borne by the user.

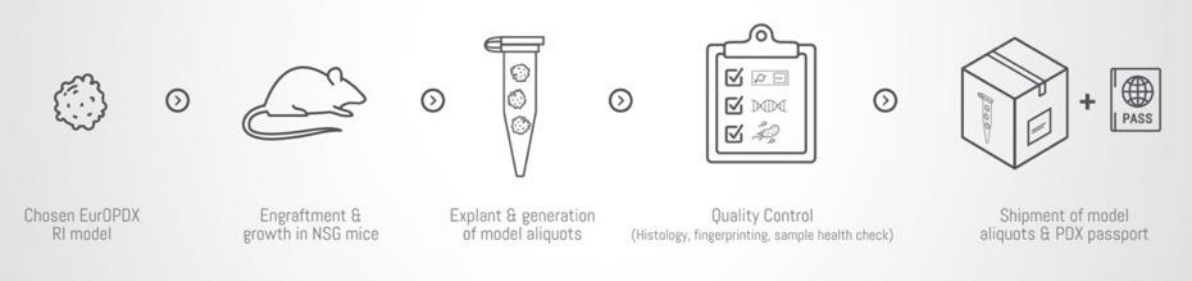

Figure 1 – Schematic illustrating the SAMPLE service

- **DEPOSIT = deposition of PDX models into the EurOPDX Research Infrastructure biobank and EurOPDX Data Portal**

The user's PDX models selected for deposition into the EurOPDX RI biobank will be health checked according to our Health monitoring SOP[1], and if cleared expanded, biobanked, and quality controlled (histology, identity check, health monitoring) in one of the six nodes according to the standards agreed within the EurOPDX RI (see Figure 2 below).

In parallel to this biobanking process, PDXs data (metadata, as well as molecular and/or pharmacological data if available) will be collected to be included in the public EurOPDX Data Portal (dataportal.europdx.eu). Each model will be accompanied by a "PDX passport", a factsheet developed by the EurOPDX RI to contain all main features of a given PDX model, such as histology, strain, growth characteristics.

[1] The Health monitoring SOP is available for download on the EurOPDX: www.europdx.eu/standards. Other SOPs developed more recently will be made available in 2020.

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Once deposited into the EurOPDX RI and Data Portal, users' models will be made available to the scientific community for TA, through the SAMPLE service described above, or at minima on a collaborative basis if properly justified by the owner of the models[2]. A grace period is possible to allow for proper publication and/or protection of a model.

The access to the DEPOSIT service is **free of charge**. However, the shipment cost of frozen vials from the user's laboratory to the designated infrastructure node must be borne by the user.

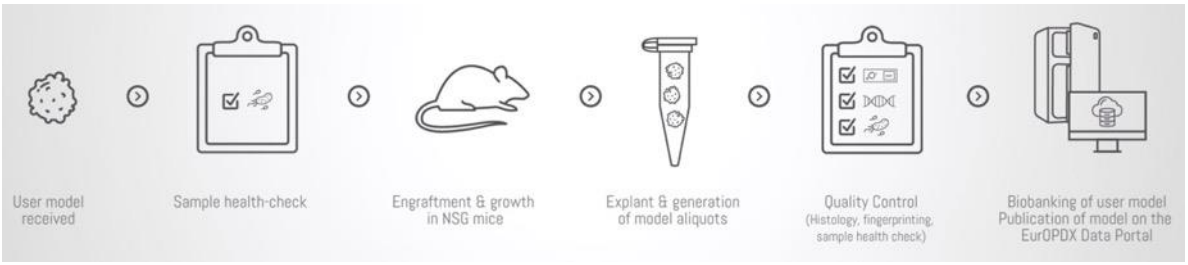

Figure 2 – Schematic illustrating the DEPOSIT service

- **TEST = performance of *in vivo* studies on selected PDX models at one of our 6 nodes**

One of the infrastructure node will be designated to perform the *in vivo* drug efficacy study for each TEST project, based on the PDX model(s) selected by the user for their particular features in the public EurOPDX Data Portal (dataportal.europdx.eu). The user will supply its drug of interest. Regular updates will be sent during the study, and an experimental report detailing the results and quality controls will be provided at study completion (see Figure 3 below).

In the TEST service, unless justified by the user upon application, each treatment arm will consist in 6 NSG mice, selected for homogeneous tumour size from 10 implants of one particular PDX model, and randomized for treatment. This design will correspond to 1 access unit. As a consequence, the testing of one drug in an *in vivo* study will require two access units (drug vs. control arm, six mice per arm), etc…

The access to the **TEST service is free of charge**. However, the shipment cost of the drug(s) of interest from the user's laboratory to the designated infrastructure node must be borne by the user.

The TEST access type if open to both Academic and Industry researchers.

[2] Successful TA proposals using models included in the EurOPDX RI will be selected by an independent committee of evaluators (TA-CE), therefore independently of the owner of the models. After selection, specific MTAs would still be signed between the owner of the models and the selected users.

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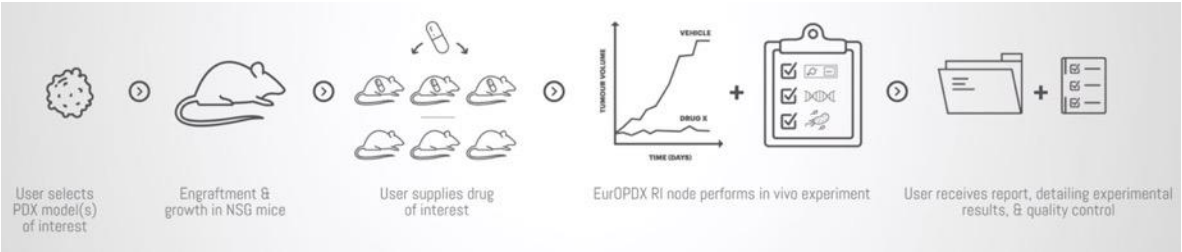

Figure 3 – Schematic illustrating the TEST service

Access to the EurOPDX Research Infrastructure under the EDIReX EU grant also comes with certain obligations for the users, that are detailed in the present Section 4.

In total, **up to 20 SAMPLE access units (i.e. PDX models) and up to 20 DEPOSIT access units** will be possible at each cut-off date, as well as **20 TEST access units** (i.e. 20 treatment arms in a PDX model).

2.2 Hands-on training

We also offer **hands-on training opportunities in the nodes** to users, primarily targeted at early career researchers and technical staff. You will be able to sign-up for it and motivate your application in the different templates (see below). The selection will be made at the same time as the projects by the Committee of TA Evaluators, based on relevance of the application and taking a careful consideration of gender balance.

At each cut-off date in 2020, **2-3 slots** for a 2-day hands-on training will be possible.

2.3 Key dates

- 14th February 2020: Opening of the 3rd and Open Call for TA. Start of submission of project proposals, which are welcome until the second cut-off date below.
- **First cut-off dates: Tuesday 31st March 17:00 CEST (Brussels time)**
  - April 2020: Evaluation of project proposals by the Committee of TA Evaluators
  - Beginning of May: Notification of successful project proposals by email
- **Second cut-off dates & Closure of the Open Call: Tuesday 16th June 17:00 CEST (Brussels time)**
  - Mid-June to mid-July 2020: Evaluation of project proposals by the Committee of TA Evaluators
  - Approx. mid-July: Notification of successful project proposals by email
- Upon confirmation of selection for access to the EurOPDX RI to successful applicants, finalisation of model selection and study design where needed, and set-up and signature of user access contract & additional paperwork such as ethics considerations, required before implementation of TA.
- From the confirmation of selection for access to the EurOPDX RI to successful applicants, **SAMPLE AND DEPOSIT access can be expected to be completed**

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approximately 4-6 months after completing all necessary paperwork, 9 months for TEST access.

3. Application for TA & Selection procedure

3.1 How to gather information

All details about the EurOPDX RI and the project proposal procedure can be found in this "Guide for applicant" and via the EurOPDX RI webpage: www.europdx.eu/europdxri-ta

Selection of PDX models of interest should be performed using the newly developed EurOPDX Data Portal: dataportal.europdx.eu

Please note that new models are continuously being added to the Data Portal, and we expect a new data release in the Spring 2020. **If the models you are looking for are currently missing, please do not hesitate to contact us** at ta@europdx.eu.

You can register your interest in the call and provide your email address to receive updates and related documents here: www.europdx.eu/europdxri-ta

We are also available to answer your TA-related questions via our **dedicated helpdesk** at: ta@europdx.eu.

3.2 Eligibility

Proposals to the EurOPDX RI TA call can be submitted from **applicants around the world, including EU Member States and Associated Countries[3], as well as third countries**. Up to 20% of successful projects can be allocated to applicants from third countries.

3.3 How to apply

Applications must be written in English, using the application templates available for download on the webpage: www.europdx.eu/europdxri-ta.

The application process is simple and includes general questions about the user research group, the PDX models to be received, deposited or used in your proposed *in vivo* drug efficacy study, the project proposal attached to these models, and basic ethics considerations.

The submission period opens on the 14th February 2020 and closes on the 16th June 2020 at 17:00 (Brussels time - CEST).

Please email us your proposal by the deadline at: ta@europdx.eu.

[3] https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/3cpart/h2020-hi-list-ac_en.pdf

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3.4 Application selection procedure

We established a **Committee of TA Evaluators (TA-CE)**, as a mixed panel consisting of external experts in the field of molecular, translational, preclinical and clinical oncology, and experts from the EurOPDX Consortium. Evaluators are covering a wide range of cancer types and expertise in the field. In total three evaluators, including at least one external expert relevant to the field, will review each submitted project proposal with respect to the following criteria:

- Scientific excellence (originality and scientific quality)
- Feasibility, notably with regard to the available preliminary data
- Expected impact (interest to the wider scientific community and societal needs)

Whilst also considering aspects such as:

- The prioritisation of new users and users who work in countries where no such Research Infrastructures exists;
- Gender balance
- Career stage of applicant.

All applications will be handled with strict confidentiality.

A scoring system is being established and will allow objective selection of successful applications.

Results of the evaluation will be sent by email.

4. Implementation of access & Obligations for successful applicants

4.1 Material Transfer Agreement & Ethics compliance

For **SAMPLE and DEPOSIT** access types, a **Material Transfer Agreement** (MTA) will need to be executed between the selected user(s) and the relevant EurOPDX RI project participants. This contract is **based on the MTA template established by the EurOPDX Consortium, which is being adapted to specificities and constraints of Trans-national Access**.

- The template **MTA for SAMPLE** access is available here: https://www.dropbox.com/sh/4wj9ssw355v9j1j/AAAXHnkIsZkhg7DVWncWMlg9a?dl=0

- The template MTA for DEPOSIT access will be available by the end of November 2019, following the same principle as for SAMPLE. Therefore, we encourage you to refer to the link above.

For **TEST** access type, a Services Contract will also be executed with each selected user. The contract template will be available end of 2019/early 2020, however main clauses are included in the TEST application template (see below).

The “Access Officers” made up of managing representative(s) from the University of Torino (Italy) and Seeding Science (Belgium) will be in charge of organising the signature of the contract for each selected TA proposal.

We also aim to be **fully compliant with applicable local, national and EU regulations regarding the establishment of PDX models, collection of personal data and performance of experiments in laboratory animals**. The Access Officers will therefore

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collect a certain number of ethics information and documents from the selected users, to verify compliance.

As soon as the above legal aspects have been fulfilled, the implementation of TA for the selected proposal can commence.

4.2 Infrastructure nodes

The EurOPDX RI is organised as a distributed infrastructure composed of **six independent nodes across six countries**, which are **state-of-the-art EurOPDX laboratories performing research using PDX models**:

University of Torino, Department of Oncology at the Candiolo Cancer Institute (Candiolo, Turin, Italy)

Katholieke Universiteit Leuven, Trace PDX platform (Leuven, Belgium)

University of Cambridge, Cancer Research UK Cambridge Institute, Carlos Caldas laboratory (Cambridge, UK)

Institut Curie, Laboratory of Preclinical Investigation (Paris, France)

Vall d'Hebron Institute of Oncology, CELLEX building (Barcelona, Spain)

Netherlands Cancer Institute, Preclinical Intervention Unit of the Mouse Clinic for Cancer and Ageing (Amsterdam, The Netherlands)

The nodes are implementing our common standards and procedures for PDX biobanking, quality control, and *in vivo* studies, and will also offer training in this area as from this 2nd TA call. The SOPs are made available on the EurOPDX RI webpage as they become available (www.europdx.eu/standards).

The EurOPDX Access Officers will allocate a node to each successful proposal according to internal criteria and constraints under the grant.

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4.3 User obligations

Once the selected TA Project has been accomplished, each Lead user will be requested to provide the Access Officers, via the contact email: ta@europdx.eu, the following information:

a) TA feedback form

A few weeks after completion of access per se (i.e. receipt of frozen PDX samples under SAMPLE, DEPOSIT of user models, or completion of TEST access project and receipt of final report), we will be sending you a feedback form. This form is very important to help us evaluate and improve our services.

b) Dissemination of TA results & Acknowledgement of the EurOPDX Research Infrastructure

Research results benefitting from TA must be published as a peer-review article and/or through poster/oral presentations at conferences. Please consider publishing in open-access journals.

Outcomes (publications, presentations, patents, etc.) resulting from work carried out under the EurOPDX Research Infrastructure TA activity **must include the following funding acknowledgement**: "*Part of this work has been funded by the European Union's Horizon 2020 research and innovation programme (Grant agreement No 731105)*". Please also **mention specifically the EurOPDX Research Infrastructure** as providing the service in any publication resulting from the TA activity.

c) TA Activity Report

At the end of your project as planned in the executed MTA, you will be asked to provide a short but detailed report describing the objectives, methods, and results of your TA project, including how the TA award has furthered your/your labs wider research objectives.

d) Inclusion of (part of) TA data in the EurOPDX Data Portal

At least part of the data generated through TA activities using PDX models from the EurOPDX RI should be included in the EurOPDX Data Portal, to further benefit the scientific community and avoid duplication of efforts. A grace period may be granted to allow for proper publication and/or protection of results.

e) Participation to a User Feedback Workshop

Users will be encouraged to attend a User Feedback Workshop to present outcomes and experiences of their access at the EurOPDX Research Infrastructure. Suggestions for improvements will be taken in consideration for the next TA calls and for future developments of the Infrastructure. Further details will be made available in due time.

4.4 Support & Consulting services

The nodes will provide extensive user support beyond the basic TA service:

SCIENTIFIC & TECHNICAL SUPPORT: For users selected under SAMPLE, detailed consulting will be made available for the design of the drug efficacy study in-house, covering all aspects of the experimental procedures from animal handling/health, to number of mice per arm, to generation and interpretation of preclinical and molecular data. Ethics consulting

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will also be provided. Users will benefit from support of the EurOPDX RI in the finalisation of their TEST access project as well.

Technical support will be provided for the handling of PDX samples however the users should first refer to our SOPs when available online.

LOGISTICAL SUPPORT: a **Helpdesk** (ta@europdx.eu) has been established to support applicants in their proposal preparation and throughout the provision of service by the EurOPDX RI.

5. Application guide (step-by-step)

The application system consists of **three steps**:

a. Download application template

Navigate to the EurOPDX Research Infrastructure website (www.europdx.eu/europdxri-ta) **and download the application template.**

Identify which type of access you would like to apply for: either "SAMPLE", "DEPOSIT" and/or "TEST".

Then:

For SAMPLE: use the EurOPDX Data Portal (dataportal.europdx.eu) to identify a model (or models) of interest to you

For DEPOSIT: collate all available information on the model(s) that you are interested in having archived with the EurOPDX RI biobank and Data Portal repository

For TEST: use the EurOPDX Data Portal (dataportal.europdx.eu) to identify a model (or models) that you would like to be tested in your proposed *in vivo* study

Please read this Guide for Applicants, the relevant application template, and the information available on the website carefully before beginning to fill in the form.

b. Fill application form

This is the sole form of submission for this access call and will be subject to the TA Committee of Evaluators review.

The form is composed of several sections, all of which are mandatory. The application must be filled out entirely using: Font – "Arial", Font size: "10".

If you have any doubt about the form content, feel free to contact directly the Help Desk service at ta@europdx.eu

c. Confirm and submit proposal

Please review your project proposal carefully before submitting. If you have any questions, contact our **Helpdesk** at ta@europdx.eu. Once finalised, the **completed application form must be returned by email to** ta@europdx.eu. – Confirmation of proposal submission will be sent by the access officers within a week of submission and confirmed upon reaching each cut-off date.

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6. Application forms description

Part 1 – Lead user

Lead User: in this section all the details about the leader of the user group should be given. Description of career path and list of up to 5 relevant publications will be used, in part, to assess the capabilities of the user to deliver on the project that they have proposed. Therefore, you are invited to provide information that allows the Committee of Evaluators to judge if the project is feasible and of a suitable scope. Applicants are strongly encouraged to focus on their own research to show their strength in the field, but can include relevant high-impact references from other groups.

Part 2 – User group

User group: All individuals who have/or will contribute to the proposed project should be listed here. These data are required by the EC for statistical purposes. For this reason, applications can only be considered if all such data are provided.

Part 3 – Access units focus

Access type requested will be pre-filled with SAMPLE, DEPOSIT or TEST depending on which application form you have downloaded.

For SAMPLE, you will need to specify the number of models requested, and then provide information on the specific models that you have requested, including the platform the model is listed in (e.g. EurOPDX Data Portal), the model ID (e.g. CRC0098LM), and the cancer type (e.g. Colorectal).

For DEPOSIT, you will need to specify the number of models that you would like to have deposited, and then provide a full and precise description of each PDX model, for instance, including: Cancer type, Tumour type, if already in a repository: model ID and repository name, any accompanying molecular data type available (e.g. Targeted NGS, RNA Seq).

For TEST, you will need to specify the number of access units requested, and then provide information on the specific models in which you would like to have the drug efficacy study performed, including the platform the model is listed in (e.g. EurOPDX Data Portal), the model ID (e.g. CRC0098LM), and the cancer type (e.g. Colorectal).

For SAMPLE and TEST, if you cannot find the relevant models for your project in the EurOPDX Data Portal, please email us at ta@europdx.eu before starting the application process so we investigate if those models are still available from EurOPDX partners.

Please note that only a limited number of access units are available within this call. Please provide adequate justification if applying for numerous access units within a single proposal.

Part 4 – Project proposal

This is the core section for evaluation of proposals. This section is meant to give the TA-CE a general overview of your proposed project, for which they will evaluate novelty, scientific excellence, scientific impact, innovative aspects, feasibility, and scope. You must provide:

Project title – provide a succinct title for your proposal

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For SAMPLE:

Description of the project – max. 1000 words
1) Briefly introduce the state-of-the-art in relation to your project
2) Describe the available *in vitro* and *in vivo* preliminary data and scientific objectives of the proposal
3) Describe explicitly why access to the EurOPDX Research Infrastructure and the model(s) requested is/are relevant to your proposal
4) Describe the potential impact of the project
5) Describe your plan for dissemination and exploitation of the expected results, including any potential protection and industry developments.

Work plan – max. 700 words
1) Describe the technical work plan of the project, outlining tasks and methods
2) Provide a detailed timeline for the project and a Gantt Chart, with milestones and deliverables
3) Describe the feasibility of the project in terms of lead user/user group capabilities

For DEPOSIT:

Description of the project – max. 800 words
1) Introduce the state-of-the-art for research with regards to the cancer type(s) and model(s) that you wish to deposit within the EurOPDX Research Infrastructure
2) Describe any novelties of the model(s) that you wish to deposit
3) Describe the importance of your model in terms of the research that can be carried out on it
4) Detail your reasons for wanting to deposit your model within the EurOPDX Research Infrastructure biobank, and how such as deposition will benefit the wider PDX research community

Method used to generate the model you wish to deposit - max. 500 words
1) Describe, in detail, the methods used to develop the model that you wish to deposit, including validation methods and quality controls (histology, DNA fingerprinting, health monitoring).
2) Include descriptions of the methods used to generate secondary data (molecular characterisation data, drug dosing studies) that accompanies your model, referring to published articles if relevant.

For TEST:

Description of the project – max. 800 words
1) Briefly introduce the state-of-the-art in relation to your project
2) Describe the scientific objectives of the proposal
3) Describe explicitly why access to the EurOPDX Research Infrastructure and the model(s) requested is/are relevant to your proposal
4) Describe the potential impact of the project
5) Describe your plan for dissemination and exploitation of the expected results, including any potential protection and industry developments.

Study design – max. 700 words
1) Describe the available *in vitro* and/or *in vivo* data supporting feasibility of the *in vivo* study

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2) Provide information about any *in vivo* toxicity study already performed with your drug of choice (protocol, mouse strain, results obtained)
3) Justify if you consider that we would need to deviate from our standard TEST study design (for each access unit/treatment arm, 6 NSG mice, selected for homogeneous tumour size from 10 implants of one particular PDX model, and randomized for treatment).

Hands-on training – max. 100 words (FOR ALL ACCESS TYPES)
If you would like to apply for a 2-day hands-on training session in one of the 6 infrastructure nodes, please motivate your application here. Please note that this opportunity is primarily offered to early-career researchers and technical staff.

Part 5 - Dissemination exceptions

One of the obligations for projects funded by the European Commission under Horizon 2020 Programme is the accomplishment of wider dissemination as well as the provision of open access to research results. Accordingly, it is explicitly requested, as part of the EurOPDX research infrastructure access agreement, that users widely disseminate and provide open access to scientific results deriving from this access program, or to precisely describe why they don't agree to. The TA-CE will judge submitted projects on their dissemination plan, and/or the reasons given for not disseminating results.

Where the answer is given as "no" to any of the stipulations, an explanation must be given.

Part 6 – Ethical (and health) considerations (FOR SAMPLE and DEPOSIT ONLY)

It is important that the user/user group has considered, understood, and where necessary taken or proposed action to mitigate any ethical issues that may be associated with their project.

In Part 6, you must provide all necessary information to allow the committee of evaluators to judge whether your proposal meets EU and/or national ethical guidelines.

For SAMPLE – max. 500 words – considerations must cover all planned experiments

For DEPOSIT – max. 800 words – considerations must cover; the patients from whom models have been established, the protection of personal data, the animals used in model establishment, and the health status of the animal facility where models were produced.

Part 6 – Services contract – Results ownership clauses (FOR TEST ONLY)

The template services contract will be made available early 2020. In the meantime, users are invited to review the starting results ownership clauses, provide agreement in principle or justify.

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Annex I – Glossary of terms

Committee of TA Evaluators (TA-CE) – Committee established to select successful applicants for access to the EurOPDX Research Infrastructure's services.

EDIReX – "EurOPDX Distributed Infrastructure for Research on patient-derived cancer Xenografts": the funding acronym for the EurOPDX RI project (EU Grant No. 731105).

EurOPDX RI – EurOPDX Research Infrastructure

SOP (Standard Operating Procedures) – The EurOPDX Research Infrastructure is developing SOPs that will be made available on the project website.

Trans-national access (TA) – A funding scheme provided by EU Horizon 2020 aimed at ensuring "free of charge access to the best European research infrastructures".

Infrastructure node – One of the six state-of-the-art EurOPDX laboratories or facilities delivering access to models under the EurOPDX RI.

Access officer(s) – Project management representative(s) from the EurOPDX RI, in charge of helping with the implementation of TA and follow-up.

Node access officer – Project representative and point-of-contact at the relevant EurOPDX Research Infrastructure node, nominated once successful projects have been selected.

Lead user – Leader scientist of the TA proposal, main point of contact for access officers, and person responsible for delivery of the project if selected.

Unit – One unit of access corresponds to material from one PDX model received by a user (SAMPLE) or sent by a user to the EurOPDX RI for deposition (DEPOSIT).

User group – Other beneficiaries of or contributors to the proposed TA project, whereas from academia or industry.

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