Dear Researcher:

The bioMérieux PPLS Program is comprised of bioMérieux-Initiated Research (BIR) and Investigator-Initiated Research (IIR) studies. The PPLS Program is open globally to all academic and community-based physicians and researchers (internal and external) interested in conducting research related to bioMérieux diagnostic products including those of subsidiaries BioFire and Astute.

bioMérieux-Initiated Research (BIR) projects are those which are conceived, designed, implemented and supported entirely by bioMérieux, in collaboration with external partners (clinicians, researchers, universities, other companies, NGOs, etc.).

Investigator-Initiated Research (IIR) projects are those which are conceived, designed, and implemented primarily by an external party, and only partially supported by bioMérieux in a limited capacity in terms of providing any or all of the following: funding, reagents, loan of instruments, training.

Proposals must be submitted in English and are reviewed by a committee of medical and scientific staff who regularly review these proposals. Please take the time to describe the study in adequate detail so that our review committee has a good understanding of the study design, objectives, and workflow. bioMérieux may decide to support studies by providing any or all of the following: scientific expertise, funding, reagents, loan of instruments, training.

In reviewing study proposals, we consider whether the proposed study:

- Is well described and has a scientifically valid study design.
- Is aligned with bioMérieux research goals of evaluating the technical, medical, and/or economic value of bioMérieux products to patients, health care providers, administrators, laboratories, healthcare systems and/or payers.
- Provides incremental value to the current body of knowledge regarding bioMérieux products.
- Complies with regulatory requirements, ethical standards, and bioMérieux' business standards.
- Is conducted by experienced and qualified investigators.
- Is expected to result in publication in a peer-reviewed journal or other recognized professional forum within two years of initiation.

Scope of research can include, but is not restricted to, assessing laboratory workflow, assay or product performance, and important medical or economic outcomes.

We support sponsored studies to add to the body of knowledge about bioMérieux products. We do not support studies to influence individual purchasing decisions.

bioMérieux-Initiated Research (BIR) concepts and proposals could be submitted by any concerned bioMérieux employee. The BIR concept and proposal should appropriately assess

the clear need concerning evidence gaps and business goals for the review committee to make a decision.

For US investigators, bioMérieux is required by the Open Payments Act to track all transfers of value (including direct payments, the value of loaned instrument and consumables used for research purposes) it provides to covered physicians and teaching hospitals. We are required to report this data to the Centers for Medicare and Medicaid Services in March of each year. The government makes the data submitted available in a public searchable database.

Sincerely,

The PPLS Study Team at bioMérieux
PPLS@biomerieux.com

# Contents



## Section 1 - General Information

| Field | Field Type | Description |
|---|---|---|
| Title | Text | Please create a title for your submission. Please remember that the title cannot be changed once created. |
| Attestation Statement | Single Select Button | As a condition of the submission of your investigator initiated research (IIR) request, you must read and select either “I agree” or “I disagree”. If you cannot agree with the statements provided, you will not be able to submit your proposal. |
| Type of Submission | Single Select Button | Selection required to submit |
| Are you the Principal Investiagtor? | Yes/No | If yes, please upload a current copy of your CV with submission. If no, please provide PI information in the provided text fields, and upload a copy of the PI CV with the submission. |
| Please list any sub-investigators, other than you, below | Table | Click the « + » to add study personnel to the table. Click the pencil icon to edit selected rows. Click the trash icon to delete selected rows. |

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|---|---|---|
| In which countries will the study research take place? | Multiple Select Button | Choose country/countries by first selecting the Region button, then selecting specific countries within that region. Multiple regions and countries can be selected. |
| Name of Study Site(s): | Text | For IIR, please include the selected site(s) where the study will be completed. For multi-center studies, include coordinating center. For BIR, please include select site(s) if applicable. |

## Section 2- Study Information

| Field | Field Type | Description |
|---|---|---|
| Study Type | Single Select Button | IUO/RUO refers to investigational (research) use only. IVD refers to in-vitro diagnostics |
| Diagnostic Area | Single Select Button | Please indicate diagnostic area based on your PRIMARY objective. Use «Other » to identify additional products if your study involves multiple diagnostic areas |
| Products | Multiple Select Button | |
| Study Objective | Text | Identify the primary objective of the study and describe the specific aims of the study (no more than 3). |
| Study Summary | Text | For BIR concepts, please include the potential study design, estimated enrollment numbers, etc in this summary. For IIR studies, please write a brief synopsis of the proposed study |

## Section 3- Design Details

| Field | Field Type | Description |
|---|---|---|
| Study Design | Multiple Select Button | |
| Indicated Use | Single Select Button | |
| Type of Control | Multiple Select Button | |
| Study Duration | Text Table | Enter all values in months. Enter « 0 » if not applicable. |
| Target Sample Size | Text Table | Enter your total sample size in the first row. Enter your treatment and control sample size in the following rows. Enter « 0 » if not applicable. |

## Section 4- Study Details

**NOTE : <u>Please complete ALL of the following prompts. Submissions lacking sufficient information will not be considered for support.</u>**

| Field | Field Type | Description |
|---|---|---|
| Narrative description of the overall study design | Text | Please provide rationale (include evidence gap) and background information. Include any references if necessary. If applicable, describe current patient management and treatment practices and how the results are expected to impact patient management. For BIR( biomerieux initiated research) studies please also include how the proposal meets both evidence gaps and business goals as well as include summary of existing published evidence. |
| Primary/Secondary Endpoints | Text | Describe what is being evaluated through the processes listed in this application. If there is more |

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|---|---|---|
| | | than one endpoint to be evaluated, please list in bullet form. |
| Main Inclusion/Exclusion Criteria | Text | Describe study population details (e.g. ICU patients, etc.). Include the criteria for both patients and/or samples as necessary. Please include the target population. |
| Study Procedures/Data Collection | Text | Please provide detailed study/data collection procedure including the following information 1). The sample types and collection proces including where samples will be obtained (inpatient, outpatient, ED, retrospective with archived samples), who obtains them. 2) Describe allocation plan of subjects for enrollment (if applicable). 3) How many samples/tests will be collected from each subject (ie serial collection timepoins) 4) How will samples be transported to the testing location, including tineframe between collection and testing. Where will the sample be tested. 5) Describe other testing to be performed as part of standard of care 6) If applicable, how will results be reported to the clinician (including timeframes). |
| Describe known limitations to the study design and how they may affect the results. If applicable, describe how they will be addressed | Text | Please describe any and all known limitations to the study design (i.e. sample size, specific patient population, study type, analysis type) and describe what methods will be used to minimze any listed |

| | | |
|---|---|---|
| | | limitations. |
| Data Management/Statistical Plan/Data Analysis | Text | Please provide justification for sample size based on primary endpoint. Also define specific variables (including timepoints as applicable) to be evaluated and how the data will be obtained. Please provide data monitoring plan (variables, frequency, interim analysis, and resolution approach). Which statistical methods will be used in the evaluation? Who will perform the statistical analysis? Please upload the case report form or data collection sheet. |
| If the study involves a methodological comparison, provide specific information about the comparison method and how discrepant results will be resolved (if applicable): | Text | If methodoloical comparison is being used, describe what the results of the FilmArray will be compared to (i.e. conventional culture, PCR, susceptibility testing, sequencing)<br><br>If discrepant results arise, please include how you anticipate resolving (i.e. repeat testing, targeted sequencing, quality control, etc…) |
| References | Text | Provide relevant bibliographic details of last 5-7 years that support this proposal. Include any key literature referenced for this proposal. |

## Section 5- Support Requested

**NOTE : For those requesting funding, please provide a detailed budget request along with this application. Please include a break down of the total amount requested into specific categories (such as investiagtor salary, statistician salary, lab technician salary, participant reimbursement, publication costs, travel, institutional overhead percentage, etc…)**

| Field | Field Type | Description |
|---|---|---|
| Support Requested | Multiple Select Button | |
| Financial | Text | Please provide the total financial amount requested. Please select either EUR or USD using the drop down menu to the right of the text box. Please indicate if support is being requested from other sources. If yes, please use the « + » button to add other sources of funding to the table. Use the pencil icon to edit selected table rows. Use the trash icon to delete selected table rows. |
| Product | Table | Please include any details required for shipment under details, please include total quantities for the entirety of the study, please detail the estimated shipping frequency schedule (e.g. can all quantities be shipped in one shipment vs. multiple shipments?).Please use the « + » button to add product requests to the table. Please select requested products using the drop down menu. Ensure requested quantities are provided. Enter a new row to the table for each different product being requested. Use the pencil icon to edit selected table rows. Use the trash icon to delete selected table rows. |
| Other | Text | Use this selection to enter |

| | | |
|---|---|---|
| | | requests for service of instrument, technical support, training, verification reagents, and QC reagents |

## Section 6- Study Milestones

| Field | Field Type | Description |
|---|---|---|
| Has a full protocol been developed? | Yes/No | |
| Do you have Institutional Review Board (IRB)/ Ethics Committee (EC) approval? | Yes/No/NA | N/A is reserved for studies that do not require this approval (e.g. database studies). Please include the IRB/EC/other approval letter to this application. |
| Does the study require informed consent? | Yes/No | |
| Do you plan to register this study with any organization or on a public database (ClinicalTrials.gov)? If so, please specify: | Text | This is normally a requirement for publication in journals with interventional studies |
| Estimated study start date | Calendar | Please allow at least 3 months for contracting between the institution and bioMerieux. |
| Estimated study completion date | Calendar | |
| Would you be willing to provide interim data analysis? | Yes/No | Note : Progress reports/study updates at least every 3 months are a requirement for all supported studies. |
| What are your planned publications? | Multiple Select Button | |
| Expected date of the final outcomes (publication, manuscript, etc.) | Calendar | |

## Section 7- Additional Information

| Field | Field Type | Details |
|---|---|---|
| What is the proposed study timeline ? Please assume at least 3 months for contracting. | Text Table | Enter the estimated time (in months) each of the listed tasks will take to complete. |