# Frequently Asked Questions (FAQs)

These FAQs were gathered leading up to and during the June 23, 2017 Informational Webinar for the NIH Data Commons Pilot Phase Research Opportunity Announcement (ROA) RM-17-027. They are meant to supplement the FAQs already posted to <a href="https://commonfund.nih.gov/bd2k/commons/faqs">https://commonfund.nih.gov/bd2k/commons/faqs</a>.

## Informational Webinar Slides and Video

# Question

Are the slides from the 6/23/17 Informational Webinar on RM-17-026 available?

#### **Answer**

Yes slides from the 6/23/17 Informational Webinar can be viewed and downloaded from the NIH Common Fund website at:

https://commonfund.nih.gov/sites/default/files/NIH Data Commons Webinar 20170623 508 for posting.pdf

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#### Question

Is a video recording of the 6/23/17 Informational Webinar on RM-17-026 available?

# **Answer**

Links to the webinar slides and a recording of the video are available from the Common Fund website at: <a href="https://commonfund.nih.gov/bd2k/grants">https://commonfund.nih.gov/bd2k/grants</a>.

# **Budget**

# Question

Although no budget is required to be described beyond Stage 1, should the description of how to address key capabilities span the entire performance period, or just the first 180 days?

#### **Answer**

We would like potential applicants to be as specific as possible when describing proposed activities for the first 180 days. However, the application also calls for a vision statement. We expect a vision for how proposed activities will contribute to the NIH Data Commons Pilot Phase will span more than 180 days.

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### Question

While I understand that \$21 million is available on this opportunity, what is the limit on each individual project?

#### **Answer**

It is up to investigator to determine the appropriate budget for their project. NIH is not limiting the amount per project, though we anticipate it is unlikely one applicant will be able to completely and comprehensively cover all key capabilities such that only one award is made.

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# Question

What is the estimated total budget for the NIH Data Commons Pilot Phase?

#### Answer

\$21 million over a project period of 4 years, pending available funds

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## Question

Should the budgets of technology proposals include the cost to fully address scientific use cases—either as fixed amounts or as options? Or will this be addressed by post-award processes?

#### **Answer**

The scientific activity and the budget should align to demonstrate that the proposed plan is both realistic and achievable within the agreement award period.

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# Question

Should budgets include any estimates for work to be performed after the first 180 days?

#### **Answer**

The Research Opportunity Announcement does not require estimates for work to be performed after the Stage I (180 day) period.

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# Question

Does the program prefer small budgets that will be easy to piece together after the all-hands meeting, large budgets to assure that a substantial percentage of the capabilities are going to be addressed, or neither of the above?

The Program does not have a preference and all budgets should align with the research activity proposed.

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## Question

Would it be helpful to explicitly include technology and budgeting options to be considered during the evaluation stages, including at the meeting in October? If so, how would NIH staff recommend that applicants declare these options?

#### **Answer**

The application should include a well-justified, reasonable budget for the first 180 days of the project. NIH is letting applicants decide how best to describe that budget. Additional budget information beyond the first 180 days is not helpful.

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#### **Answer**

Potential applicants are expected to propose and justify a budget for the first 180 days of the NIH Data Commons Pilot Phase (Stage 1). It is up to the potential applicant to propose a budget s/he believes will reasonably support the proposed approach to address one or more key capabilities for the Data Commons.

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### Question

Related to the sharing of funds between the academia and the industry. The personnel cost in the industry is definitely higher in comparison to the academia and as a result, we have to allocate substantial funds for our industry partner(s). Can you advise regarding this type of arrangements with industry? Is there a limit in the total amount of distribution between academia and the industry?

#### **Answer**

Applicants decide on the budget that is needed. We're encouraging collaborations or individual applications from industry and are aware that there are cost differentials. Distribution of costs between academic and commercial groups is not capped. Staffing and Budgets submitted have to be well justified according to the need within the project.

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#### Question

Do you want budgets proposed for the full 3-4 years or just for the first 180 days?

# Answer

Budgets are only requested for Stage 1 (the first 180 days) of the NIH Data Commons Pilot Phase. Proposed budgets for Stage 2 (after the first 180 days) are unlikely to be meaningful as the NIH Data

Commons Pilot Phase Consortium will do an evaluation of Stage 1 and make necessary adjustments before implementing Stage 2.

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Test Case Datasets – Model Organism Databases (<u>MODs</u>), Trans-Omics for Precision Medicine (TOPMed), and Genotype Tissue Expression (GTEx)

#### Question

Are there resources to learn more about the test case datasets: MODs, TOPMed, and GTEx?

## **Answer**

Visit the websites for each dataset (most of these links were also provided in the Research Opportunity Announcement)

Model Organism Databases (MODs): <a href="http://www.alliancegenome.org/">http://www.alliancegenome.org/</a>

Trans-Omics for Precision Medicine (TOPMed): <a href="https://www.nhlbi.nih.gov/research/resources/nhlbi-precision-medicine-initiative/topmed">https://www.nhlbi.nih.gov/research/resources/nhlbi-precision-medicine-initiative/topmed</a> see also <a href="https://www.nhlbiwgs.org">www.nhlbiwgs.org</a>. This is the project's working web site. It has publicly available pages that describe each of the participating studies.

Genotype Tissue Expression: <a href="https://commonfund.nih.gov/GTEx/index">https://commonfund.nih.gov/GTEx/index</a> see also <a href="https://www.gtexportal.org/home/">https://www.gtexportal.org/home/</a>, which provides more information about GTEx datasets.

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# Question

Being cancer focused, will this be responsive to this OT3 mechanism? If you are looking for non-cancer projects only (GTEx, TopMed and MODs being primary examples cited), this may not be the mechanism for what we propose here.

# **Answer**

The current Commons Pilot Research Opportunity Announcement is only addressing the 3 existing data sets GTex, TOPMed, MODS. We want to create some tests in this area first before considering which additional data sets we'd include. We realize the community has a broader interest in this and there are plans to reach out to the community to better assess the needs for the moment our focus remains on the current ROA.

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# Question

The capability to collect and curate data is missing from the funding announcement. Is that because NIH expects much of the curation would be handled through existing Data Coordination Centers of funded programs and other NIH collection activities?

NIH expects curation of the selected test case datasets to be handled in collaboration with the Data Coordination Centers for each dataset.

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# Question

The database of Genotypes and Phenotypes (dbGaP) doesn't allow redistribution of its data. If we get data from dbGaP, how do we deal with that in this context?

#### **Answer**

One of the challenges for the NIH Data Commons Pilot Phase Consortium is to figure out how to integrate authorization and authentication processes for access-controlled data into a commons environment.

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#### Question

Readily accessing the resources (through API/webservices) will be key to stand up during Stage 1. Have the 3 test case datasets been tested for access by cloud-based solutions, or will this also need to be assessed early on as the Data Commons Pilot Phase Consortium (DCPPC) forms?

## **Answer**

We anticipate in the initial stage the consortium will leverage existing APIs and tools to accelerate making data from the datasets available. The intent is for the initial stage to develop a "minimally viable product" that demonstrates capability, which could be a very limited set of data, phenotypes, lower fidelity APIs etc.

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# Question

How were the Model Organism Databases (MODs), Trans-Omics for Precision Medicine (TOPMed), and Genotype Tissue Expression (GTEx), test case datasets chosen?

### **Answer**

NIH leadership chose to focus initially on high value, high volume datasets for the Data Commons Pilot Phase. The three selected datasets meet these criteria, and represent the interests of multiple NIH Institutes and Centers. If potential applicants have additional datasets that would add value to the work being done on the three selected test case datasets, they can propose their use as part of their proposal, but they must be well-justified.

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# Question

Is it required that the applicant must work with one of the test case datasets (MODs, TOPMed, GTEx), or are these just examples of datasets that can be used?

#### **Answer**

Yes, it is expected that members of the NIH Data Commons Pilot Phase Consortium will work with one or more of the selected test case datasets. Additional datasets that increase the utility of Data Commons Pilot Phase test case datasets (TOPMed, GTEx, and MODs) may be included in an applicant's response; however, additional datasets need to be fully justified and NIH must approve use of funds to work with other data sets.

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# Question

Is a partnership with existing scientific users of the three test case datasets (MODs, TOPMed, GTEx) required, or are those partnerships expected to evolve during Stage 1 (the first 180 days) of the NIH Data Commons Pilot Phase?

#### **Answer**

It is not required for potential applicants to have existing relationships with the three test case datasets chosen for the NIH Data Commons Pilot Phase. It is expected that partnerships that did not exist before awards are made through RM-17-026 will develop over the course of Stage 1 (the 180 days) of the NIH Data Commons Pilot Phase.

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## Question

How do we know the size and number of users accessing the 3 test case datasets (MODs, TOPMed, and GTEx)? Or should we find out that information on our own?

#### **Answer**

Examples should be given where multiple users need to use the resources simultaneously, and the solutions should be tested.

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# **Teaming and Collaboration**

### Question

For a single, collaborative application involving multiple organizations, in the event of an award, could each organization be funded directly by NIH?

# Answer

NIH will issue only one award and the members will be subcontractors to one lead. NIH will not issue individual actions.

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#### Question

Should plans explicitly incorporate relationships to individuals and organizations from the three-targeted high-value data sets (MODS, GETx, and TOPMed), for example by citing related past work, or including letters of support?

#### **Answer**

Potential applicants are not required to have collaborated with individuals or organizations from the three test case datasets. Information about past collaborations can be included in the Letter of Intent and application. However, remember that applicants are limited to only 2 letters of support.

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#### Question

When fashioning a project team, should technology developers seek out scientists who might use those technologies?

#### **Answer**

This depends on what the applicant wants to address as part of the key capabilities of the NIH Data Commons Pilot Phase. It is not required for technology developers to include potential end users on their team. However, plans for engaging the community are a scorable component of the application.

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#### Question

Can NIH help me find collaborators for my application to RM-17-026?

# **Answer**

No, applicants must submit their own plans for collaboration to address the Key Capabilities described in RM-17-026.

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#### Question

Should applicants attempt to link their proposals to other proposals? Will it strengthen a proposal to note synergies between two proposals submitted by two different PIs?

#### Answer

The NIH Data Commons Pilot Phase Consortium will have to work nimbly as a team. While it is not required to link a proposal to other proposals, noting synergies where they exist, is encouraged.

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# Question

Related to the sharing of funds between the academia and the industry. The personnel cost in the industry is definitely higher in comparison to the academia and as a result, we have to allocate

substantial funds for our industry partner(s). Can you advise regarding this type of arrangements with industry? Is there a limit in the total amount of distribution between academia and the industry?

#### **Answer**

Applicants decide on the budget that is needed. We're encouraging collaborations or individual applications from industry and are aware that there are cost differentials. Distribution of costs between academic and commercial groups is not capped. Staffing and Budgets submitted have to be well justified according to the need within the project.

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### Question

Will single applications involving multiple institutions be allowed?

#### **Answer**

Yes.

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# Question

Is the NIH's preference that we put in 4 separate proposals addressing different Key Capabilities or is the preference to wrap them into a modularly organized single proposal?

### **Answer**

Potential applicants should submit Letters of Intent and applications they think are appropriate and will provide the most scientifically valid approach. Submitting multiple separate proposals to increase the odds of receiving an award is not a good approach.

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#### Question

Can you please confirm that an umbrella approach will be welcomed, or is there a preference for groups to construct more focused proposals?

#### **Answer**

The NIH does not intend to be prescriptive about the way potential applicants self-organize to develop applications. It is up to the potential applicants to decide how best to identify partners and collaborations (or not) to develop a robust proposal to address the key capabilities.

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# Question

Are there any limits on how many PIs can participate in the project?

No, potential applicants are allowed to organize their team as they see fit, though key personnel should be well-justified and have available effort to devote to the project. The team will need to have an identified lead who will represent the team to the government.

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## Question

Is involvement of domain experts required in the proposal?

## **Answer**

It may be useful for interpretation of the results of a use case to have an independent expert interpret the analysis result in the capacity of a domain expert.

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## Question

Is there a team size that you would consider to be a reasonable minimum or maximum for a competitive Letter of Intent?

#### **Answer**

There no ideal team size for a competitive Letter of Intent. Applicants must describe and justify why the team they have proposed is ideal to carry out proposed activities to address the key capabilities of the NIH Data Commons Pilot.

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#### Question

Is there going to be a coordination step after the Letter of Intent stage to connect potential partners?

## **Answer**

No. It is the responsibility of all "potential partners" to organize themselves as a consortium if so desired.

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#### Question

As a company, will I be able to work in isolation except for obligate meetings, or will I be expected to collaborate heavily as part of the NIH Data Commons Pilot Phase Consortium?

#### Answer

Each member of the Consortium is expected to collaborate with the other members. Working mostly in isolation is not a viable option for what the NIH Data Commons Pilot Phase hopes to achieve.

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# Question

Should multi-institution teams submit separate Letters of Intent or come in with one joint Letter of Intent.

#### Answer

Groups who intend to work together to address key capabilities of the NIH Data Commons Pilot Phase, should submit one joint Letter of Intent.

To be clear, the Other Transaction Agreement is a bi-lateral (i.e., two party) agreement between the government and a single entity, which is responsible for performing the identified work consistent with all associated terms and conditions of the award. If your group is not already established as a legal entity (i.e., incorporated), you will need to identify a lead entity to execute this agreement, receive and distribute payments, and represent member organizations in negotiations with the government. Therefore, groups proposing at the LOI stage may wish to begin considering how they will organize themselves in case they are invited to submit a formal application.

If your "non-legal entity" group or consortium is invited to submit a formal application after the LOI stage, it is highly recommended that, prior to submitting an invited application, you formally establish your consortium through an articles of collaboration, teaming agreement, or other written documentation that ensures that member roles and responsibilities for completing work are clear, funds distribution to members is understood from the onset, sharing and use of intellectual property among members is defined, etc.

Although the government has an interest in ensuring consortia are able to manage themselves effectively, each consortium is responsible for organizing itself. The government has no desire to impose a particular organizational format or set of terms by which consortia should govern themselves.

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# Question

Any recommendations for PIs being part of multiple applications?

#### **Answer**

PIs are allowed to be part of multiple applications, but their total effort for all NIH-supported projects, including the multiple NIH Data Commons Pilot Phase projects, should not exceed 100%.

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# **Developing Use Cases**

# Question

I noticed that the National Heart, Lung, and Blood Institute (NHLBI) will administer this funding opportunity and that one of the three test case datasets, TOPMed, is supported by NHLBI. Should I tailor the use cases I develop for my application to be relevant only to NHLBI?

While NHLBI is an active participant in the NIH Data Commons Pilot Phase, multiple other NIH entities are funding and organizing this effort. Proposed use cases should demonstrate knowledge of how the three test case datasets might be used if they were made available in a commons environment. This is not limited to research questions of interest exclusively to NHLBI. The example use case given in the Research Opportunity Announcement is only an example. Proposed use cases do not have be modeled on the example.

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### Question

How are the use cases from section 8 expected to impact the development of the data commons?

#### **Answer**

The use case in the Research Opportunity Announcement is provided as an example only, we expect proposers to submit other use cases. Use cases provide a demonstration of how the functional aspects of a research question drive solutions to the technical aspects underlying the analysis. For example, standardization in the Data Commons to make data from different sources comparable is an aspect that may emerge when solving a use case.

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# Personnel

# Question

Should key personnel described in the Letter of Intent and full application work full-time on this project?

#### **Answer**

It is up the potential applicant to decide how to appropriately staff any proposed work for the NIH Data Commons Pilot phase. Staff selections and their level of effort should be well-justified. Potential applicants should also ensure that the level of effort for each proposed staff member does not total more than 100% for the NIH Data Commons Pilot Phase and other current projects.

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#### Question

What level of awardee is required to attend the October 2017 Kick-Off Meeting? Only PIs? PIs and Key Personnel? Additional staff who might work on the funded research but are not listed among Key Personnel?

# **Answer**

We expect the Kickoff Meeting to have discussions about the Consortium, such as governance, tasks, etc. While we do not anticipate any breakout sessions, it may be prudent to plan for 2-3 people to attend.

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# Compliance with Rules and Regulations

# Question

Is FISMA compliance required?

#### **Answer**

Whether or not FISMA compliance is required depends on the nature of the activities being proposed. The security requirements are the same as they are for all NIH extramural activities involving controlled access data. More information on these requirements can be found on the <a href="NIH Office of Management">NIH Office of Management</a> site.

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#### Question

Will a federal-wide assurance (FWA) and institutional review board (IRB) be required to operate the Data Commons pilot?

### **Answer**

This will depend on who applies to participate in the NIH Data Commons Pilot Phase and the nature of the proposed activities. The NIH Data Commons Pilot Phase Consortium will address this issue once the participants have been identified.

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# Addressing Key Capabilities and Proposal Focus

# Question

Are the proposals required to bring along data, computation scenarios, etc.?

## **Answer**

No, proposals are not required to bring along data. Computation scenarios depends on the Key Capability being addressed in the proposal.

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# Question

Is <u>AIHPC</u> (an advanced cloud data science, machine learning and HPC product released by Amazon cloud) relevant to building the Data Commons cloud pilot?

If AIHPC is applicable to supporting one of the key capabilities, then yes, it is relevant to the NIH Data Commons Pilot Phase ROA RM-17-026. It will be up to the potential applicant to define how that can be achieved.

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#### Question

Although no budget is required to be described beyond Stage 1, should the description of how to address key capabilities span the entire performance period, or just the first 180 days?

#### **Answer**

We would like potential applicants to be as specific as possible when describing proposed activities for the first 180 days. However, the application also calls for a vision statement. We expect a vision for how proposed activities will contribute to the NIH Data Commons Pilot Phase will span more than 180 days.

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## Question

Is there an interest in in ROA RM-17-026 for development of generalized tools to be used in the commons that draws from all available datasets?

#### **Answer**

Development of new tools is not the goal of this funding proposal per se, unless new solutions are needed in building the IT resources. If existing analytic tools can be engineered into the infrastructure that would be a good approach. The major goal of this funding opportunity is to have an IT resource in place that provides the engineering solutions for interoperable cloud providers on top of which integration of IT and computational biology solutions can happen seamlessly within the Data Commons. The applications should address these technical challenges on an engineering level with sufficient understanding of the final research purposes of end users.

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#### Question

In addition to the system development, how much effort would NIH expect for the evaluation, in terms of feasibility and performance?

#### **Answer**

Stage 1 of the NIH Data Commons Pilot Phase is about developing a plan for implementing a commons. Part of the Stage 1 efforts will include the development of minimal viable product prototypes to demonstrate key capabilities of the NIH Data Commons Pilot. This will include some technology testing and development. Potential applicants should have demonstrable capacity and capability to carry out the activities proposed in their application. In particular, an approach is encouraged where small incremental development efforts are amenable to beta testing and end user feedback incorporation, in the spirit of agile development with sprints and continuous tests for launching, such that performance can be measured on a continuous basis.

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#### Question

It sounds like the intent is to provide a Data Commons "software stack" where individuals can implement one or more parts of the stack. Can you speak a little on if this aligns with your vision?

# **Answer**

We anticipate the NIH Data Commons Pilot Phase will include software, but the program will go beyond that. We are interested in demonstrating how a Data Commons pilot, including a software stack, can answer scientific questions and improve cost and efficiency.

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## Question

Could you please provide further detail on what is meant by core components of the NIH Data Commons Pilot which must be open source? What are considered to be core components?

#### **Answer**

"Core components" means all those components required to make the Commons environment useful to researchers in answering scientific questions. We encourage you to read the intellectual property (IP) related sections in the Research Opportunity Announcement (ROA) RM-17-026.

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# Question

Is there scope for actually populating the infrastructure with analytics suitable for the three listed resources (TOPMed, GTEx, MODs)? That is, to implement a suite of analytics tools that will leverage the cyberinfrastructure developed in the other key capabilities. The 'key capability' of 'Scientific Use Cases' seems to the right one for such a goal, but could you clarify if we interpret this correctly? The existing toolkit associated with the listed resources (TOPMed, GTEx, MODs) leave much room for expansion, particularly if one could go across datasets as indicated. So, is "implementing new analysis tools" rather than just "supporting their implementation" via the realization of the Commons, in scope with the solicitation?

# Answer

There is scope for populating the infrastructure with analytics suitable for the three listed resources as long as it supports the use case in a logical way. This leaves room for expansion only if it complements the elements of analysis in the proposed use case. The 'key capability' of 'Scientific Use Cases' should still be justified in the goals of a proposed project. The general goal is to build an infrastructure where researchers can bring software and ad-hoc pipelines to the big data to make efficient use of already existing high-volume and high-value data. Development of new analytics tools is not the goal of this funding proposal per se, unless new solutions are needed in building the IT resources.

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### Question

Is it acceptable to propose a well-designed system for a specific use case or does the proposed system need to be generic?

## **Answer**

The major goal of this funding opportunity is to have an IT resource in place that provides the engineering solutions for interoperable cloud providers on top of which integration of IT and computational biology solutions can happen seamlessly with the data commons. The applications should address these technical challenges on an engineering level with sufficient understanding of the final research purposes of end users, which is why use cases are expected.

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#### Question

Can a project address all the Key Capabilities?

#### **Answer**

Yes, a project can address one, multiple, or all of the Key Capabilities. All proposed work should be explained and justified as described in the Research Opportunity Announcement.

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# **Application Processes**

## Question

I am a non-traditional applicant (not an academic applicant with regular dealings with NIH), do I need to have an Authorized Organizational Representative submit my application?

#### Answer

All applicants must have their full applications approved and submitted by an official at their organization authorized to execute a binding agreement on behalf of their organization. Please note that approval by an authorized representative is **not** required for Letters of Intent.

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# Question

Does the Letter of Intent need Authorized Organization Representative (AOR) approval, or can I (the PI) submit it directly through email?

The Letter of Intent can be emailed by the PI directly to NIH at: <a href="mailto:commonspilot@od.nih.gov">commonspilot@od.nih.gov</a>. AOR approval is not necessary for the LOI.

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# Question

Was ROA-RM-17-026 posted on grants.gov?

#### Answer

No, the ROA was published directly to the NIH Common Fund website at: <a href="https://commonfund.nih.gov/sites/default/files/RM-17-026">https://commonfund.nih.gov/sites/default/files/RM-17-026</a> CommonsPilotPhase.pdf

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## Question

I was confused by the instructions on the Letter of Intent (LOI) concerning word limits for personnel versus key capabilities.

### **Answer**

For each key capability to be addressed by the potential applicant:

A description of relevant expertise for all key personnel, will not exceed 100 words per person

A description of planned activity to address the objective(s), will not exceed 800 words

A description of resources available to accomplish the activity, will not to exceed 500 words

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# Question

I'm confused about the word limit for the full application. Can it exceed 4000 words?

#### **Answer**

The 4000-word limit is for each key capability addressed in the application. Applicants are also able to submit up to 2 figures per key capability.

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## Question

We understand the Letter of Intent (LOI) can be emailed by the PI (as typically the case), but will the full application itself need to be emailed by the Authorized Organization Representative (AOR)?

### **Answer**

Yes, if you are invited to submit the full application, your organization's AOR should approve and email the application. If your organization does not have a designated AOR (perhaps because you are a non-traditional applicant) the application should be approved and emailed by an officer or employee who is authorized to enter into binding agreements on behalf of your organization.

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# Eligibility

# Question

I am a research scientist from academia and I am considering applying for this opportunity. Can I include a person on my team from a private company?

#### **Answer**

This solicitation is open to those who can address the key capabilities outlined in the Research Opportunity Announcement (ROA). It is open to academics and commercial groups. If you wish to partner with a private company, that's fine.

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#### Question

My company is interested in submitting an application for RM-17-026. Is NIH interested in receiving applications from private companies?

#### **Answer**

Yes. The NIH is interested in seeing what companies have to offer to address the key capabilities described in ROA RM-17-026. Other Transactions gives NIH more flexibility to engage non-traditional research partners.

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#### Question

Is a non-profit eligible to apply for Common Fund support under RM-17-026?

#### **Answer**

Nonprofits should fall in one of the following categories to be eligible for RM-17-026. Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

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# Question

Are there any limitations, or restrictions with the participation of Federally funded research and development centers (FFRDCs)?

FFRDCs are allowed. NIH will not award funds specifically for laboratory directed research and development (LDRD) costs. Laboratory contractors may recover LDRD costs within the total funding included in the award. Other costs will be reviewed and negotiated prior to award.

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#### Question

Can international organizations apply for RM-17-026?

#### **Answer**

Yes, international organizations can apply singly or in collaboration with United States partners for RM-17-026.

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## Question

Does participation in Stage 1 (the first 180 days) of the NIH Data Commons Pilot Phase create a Conflict of Interest for participation in Stage 2?

#### **Answer**

No, participation in Stage 1 of the NIH Data Commons Pilot Phase would not represent a COI for Stage 2. However, participation in Stage 1 of the NIH Data Commons Pilot Phase does not guarantee participation in Stage 2. Awards may be discontinued if they are not deemed critical to the consortium plans in Stage 2.

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# Question

I represent a company not involved with clinical/medical science. Our application would address technical IT solutions for the key capabilities described in the funding announcement. Is such an application of interest to NIH? Also, what would be the PI role in this situation?

### **Answer**

We would welcome your participation. The Other Transactions funding mechanisms makes it easier for NIH to engage non-traditional research partners. However, because of the scientific nature of this program, it is likely that you will need an experienced PI to lead the effort and keep it focused on the science. You may want to consider joining another consortium or forming one on your own to achieve this. If you intend to focus solely on a computing workspace or other purely technical key capability, you could serve as the PI, keeping in mind that you would collaborate with scientists in the efforts of the NIH Data Commons Pilot Phase Consortium.

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# Letters of Intent (LOIs)

## Question

I am a non-traditional applicant (not an academic applicant with regular dealings with NIH), do I need to have an Authorized Organizational Representative submit my application?

### **Answer**

All applicants must have their full applications approved and submitted by an official at their organization authorized to execute a binding agreement on behalf of their organization. Please note that approval by an authorized representative is **not** required for Letters of Intent.

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#### Question

The scoring for the Letter of Intent includes 30 points for past performance relative to the Data Commons, however the LOI structure does not include a section for past performance other than the 100-word description of relevant expertise for key personnel for each section. Is it permissible to include a brief overview of past performance either as a cover letter or as an addendum or introduction to the LOI?

### **Answer**

Yes, it is permissible to include information about past performance as part of a cover letter/addendum/introduction to the LOI.

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# Question

Given the short time we have to prepare, can additional partners be added to the proposal after the Letter of Intent (LOI) is submitted?

#### **Answer**

Yes, additional partners can be added after the LOI, and could in fact be added after award with agreement from the government. However, your Letter of Intent should demonstrate that your organization (or collaborative team) is capable of carrying out the activities you propose.

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#### Question

Is a Letter of Intent (LOI) evaluated in its entirety, or individually by key capability? Specifically, when submitting an LOI response addressing more than one key capability, will the LOI be evaluated by each

key capability individually, and invitations to submit a full application will be made for each key capability, or will the LOI be reviewed and approved/rejected in its entirety?

#### **Answer**

If you intend in your LOI to address more than one key capability, there is a section devoted solely to explaining how you expect these activities will interact. This description is important for reviewers to understand your rationale and approach to addressing key capabilities. However, the Other Transactions mechanism gives NIH the flexibility to select pieces of proposals it thinks will best meet the goals of the NIH Data Commons Pilot Phase.

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## Question

It is difficult to explain a computation architecture in limited words. May I include an illustration per key capability in my Letter of Intent (LOI)?

#### **Answer**

NIH encourages potential applicants to use links to web content in their LOIs for diagrams, video etc.

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## Question

Does the Letter of Intent need Authorized Organization Representative (AOR) approval, or can I (the PI) submit it directly through email?

#### **Answer**

The Letter of Intent can be emailed by the PI directly to NIH at: <a href="mailto:commonspilot@od.nih.gov">commonspilot@od.nih.gov</a>. AOR approval is not necessary for the LOI.

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# The Cloud

## Question

"The NIH Data Commons must allow portability of discovery and analytical tools and user interfaces between at least two cloud service providers." Would these two or more service providers would use a uniform cloud platform, or may the service providers offer heterogeneous cloud platform?

### Answer

The service providers may offer a heterogeneous cloud platform.

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# Question

A primary concern in the past for cloud resources has been controlling the use of the cloud resources by a global community, as costs are based on data access and compute. Are data available from the current cloud pilots to help inform cloud cost controls? Any thoughts on progress made in this area by current NIH cloud efforts?

#### **Answer**

Implementing cost controls for use of cloud resources will be a concern for Stage 2 of the NIH Data Commons Pilot Phase. NIH anticipates that researchers will want to bring their own compute resources to the cloud. We anticipate that the NIH Data Commons Pilot Phase Consortium will investigate the cost of maintaining a highly-used data resource in a public cloud environment. NIH is interested in defining and understanding the costs involved in data access and storage.

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### Question

If it's less expensive to store the data in a community cloud rather than on a public cloud, is that allowed?

#### **Answer**

One of our key goals is interoperability between clouds - public, community, and private. Whatever the environment is, it must support bringing compute to the data, and not require downloading the data.

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### Question

I understand that proposed technology must work on two cloud providers (i.e. proposed solution will run/function seamlessly when moved to another provider). Is this correct interpretation? Could you expand on what is desired for interoperability beyond seamless transitions among cloud providers?

### **Answer**

In high-volume datasets, the requirements for analyzing data on a large scale may be prohibitive to finish in its entirety on one cloud system. Here, the cloud interoperability would allow a seamless exchange and use of data and services among various cloud infrastructure offerings to complete the full analysis.

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#### Question

Since any cloud agnostic architecture is likely to include APIs, could you clarify the difference between Open Standards APIs (section 3) and Cloud Agnostic Architecture and Frameworks (section 4)?

Open Standard APIs are designed to address things like the access to data, pipeline orchestration etc., while the cloud agnostic APIs are related to abstracting core cloud service management APIs (storage, compute, IAM) with standard APIs that work across all cloud platforms.

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# NIH Staff Involvement in the NIH Data Commons Pilot Phase

# Question

Which NIH entities were identified during the 06/23/17 informational webinar as most involved in the NIH Data Commons Pilot Phase?

#### **Answer**

The three NIH entities mentioned during the 6/23/17 webinar were:

The National Heart, Lung, and Blood Institute (NHLBI, funder of TOPMed)

The National Human Genome Research Institute (NHGRI, administering Institute for GTEx and funder of the MODs)

The NIH Common Fund (funder of GTEx, and the OT awards made through the current solicitation)

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## Question

What are your expectations on how the artifacts developed through this Other Transaction funding opportunity (especially after 3-4 years), will interact with National Cancer Institute big data and commons-like activities?

#### **Answer**

Internal NIH conversations are ongoing to determine how multiple NIH efforts will interact and collaborate. The goal is to determine how to address data usability in a cloud environment, which is applicable to all NIH Institutes and Centers.

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# Question

I have a suggestion for how NIH could better communicate what is going on with the NIH Data Commons Pilot Phase even under the tight deadlines for the project. How do I share my suggestion with NIH staff?

NIH staff welcome your suggestions for improved communication around the NIH Data Commons Pilot Phase. Communications staff are monitoring the <a href="mailto:commonspilot@od.nih.gov">commonspilot@od.nih.gov</a> mailbox, and would like to hear from you.

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#### Question

The RM-17-026 states: "Applicants to this Announcement should note that the NIH has separate contract mechanisms to engage Trusted Partners. Awardees under this agreement are not expected to operate a controlled access process as a Trusted Partner." Who are the "Trusted Partners"?

### **Answer**

NIH policies related to external data distribution and trusted partners are in flux. Awardees under this agreement are expected to work with NIH in this regard.

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# **Review Process**

## Question

Is a Letter of Intent (LOI) evaluated in its entirety, or individually by key capability? Specifically, when submitting an LOI response addressing more than one key capability, will the LOI be evaluated by each key capability individually, and invitations to submit a full application will be made for each key capability, or will the LOI be reviewed and approved/rejected in its entirety?

#### **Answer**

If you intend in your LOI to address more than one key capability, there is a section devoted solely to explaining how you expect these activities will interact. This description is important for reviewers to understand your rationale and approach to addressing key capabilities. However, the Other Transactions mechanism gives NIH the flexibility to select pieces of proposals it thinks will best meet the goals of the NIH Data Commons Pilot Phase.

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# **Project Period**

### Question

Can you clarify what the expected project period will be?

#### **Answer**

The expected project period of the NIH Data Commons Pilot Phase is 3-4 years. Due to the flexibility of the Other Transactions award mechanism the budget period for each award made under RM-17-026 is

based on the milestones negotiated with NIH before award issuance and during award management. The budget period does not have to be one year in length.

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