

Chan Zuckerberg Initiative

SUBMISSION INSTRUCTIONS

Rare As One Request for Information: Patient Registry Data Interoperability

Some helpful information as you get started:

- This document contains:
 - [Getting started: General guidance on using the portal](#)
 - [Submitting a response](#)
 - [Submission details specific to the RFI](#)
- Please review the [Rare As One Request for Information: Patient Registry Data Interoperability](#).
- The Chan Zuckerberg Initiative uses SurveyMonkey Apply (SMAppl), and all submissions must be completed and submitted through this portal at <https://apply.chanzuckerberg.com>. SMAppl is configured to work best using the Google Chrome browser. The portal will allow you to save your work, so you can familiarize yourself with the portal and the submission questions in advance and return to it as you progress.
- **Key dates:**

| | |
|---------------------|--|
| September 29, 2021: | Submission portal opens |
| November 30, 2021: | Submissions due by 5 p.m. Pacific Time |

GETTING STARTED

Account setup: The submitter (i.e., the person completing the RFI submission) must first set up an account in the CZI online portal at <https://apply.chanzuckerberg.com/>.

To set up an account:

1. Go to <https://apply.chanzuckerberg.com/>.
2. Click the green **Register** button in the upper right corner.
3. Complete the requested fields and then click the green **Create Account** button.
4. Click the green **Continue** button to proceed to the site.

Please note you will need to verify your account through the auto-email that you receive after registering. You will not be able to submit until your account is verified.

Personal data: Where we ask for personal data of individuals, please only submit personal data that you have a right to provide. We will use and store any personal data collected through the submission process for program-related purposes (e.g., administering the RFI, analyzing and improving our strategies, identifying connections across the field). The Chan Zuckerberg Initiative Foundation and Chan Zuckerberg, LLC (collectively "CZI") will be the "data controllers" for any such personal information, and the data may be stored on servers outside of your home country, including within the United States. If you have any questions or concerns regarding our privacy practices or collection or use of personal data, you can contact us at privacy@chanzuckerberg.com.

Navigating the portal: Once you have set up an account, you can log in to the portal at <https://apply.chanzuckerberg.com/>. Using the links in the upper right corner, you can access available programs (which includes RFAs and RFIs for all CZI areas, not just Science) and any applications or submissions you have in preparation or previously submitted. Use the information ("i") link to get help with the portal. To access your account information, click on your name in the upper right. Your submission will pre-populate with the name and email listed in your account information so if you need to edit it, click on your name in the upper right corner to make any necessary changes.

Forgotten username or password: If you have forgotten your username or password, please navigate to the portal at <https://apply.chanzuckerberg.com/> and click on the Log In link located in the upper right corner. Click the Forgot your password link and then enter the email address associated with your SMAApply account. You will then receive an email with information to reset your password. Please note that your username is your email address.

Other questions: If you have other questions about using the portal, please use the information ("i") link in the upper right corner of the window. Here you will find a link to FAQs about using the portal, as well as links to submit specific help requests. If you have specific questions about the RFI, please contact us at rareason@chanzuckerberg.com with the subject line: RAO RFI.

SUBMITTING A RESPONSE

To make a submission:

1. Go to <https://apply.chanzuckerberg.com>.
2. Log in.
3. Click the green View Programs button that is displayed or click on the Programs link in the upper right corner. This will bring you to a listing of all programs, RFAs, and RFIs that CZI is hosting in SMAApply. To **find the RFI** you are looking for, you may need to scroll down.
4. Find the RFI you are interested in and click the green More button.
5. Click the green Apply button in the upper right and complete all sections (details below).
 - a. The submission is made up of several sections called **tasks** that are listed in a menu on the left side of the page. You can edit and complete tasks in any order. To **open a task**, click on the one you would like to work on in the table on the left hand side. You may need to scroll down to see the remaining tasks.
 - b. Once you **complete a task**, click the green Mark as Complete button within the task. To **navigate to the next task**, click on the one you would like to work on in the table on the left hand side. All required tasks must be marked as complete before submitting. To **edit a task** after marking it as complete, click the three dots in the upper right of the task and select edit, which will re-open the task.
 - c. Your submission will autosave every few seconds, but you can also click the Save & Continue Editing on each task as you go along to **save your submission**.
 - d. In the tasks that allow a PDF upload: If you need to **delete and replace a PDF** after you have uploaded it, click on the three dots to the right of the file under the Attach File section within the task and select Remove from the dropdown menu.
 - e. To **download your submission**, click on the three dots in the upper right corner of the application page and select download. If you are within a task, first click on the Back to application link in the upper left. Please **be aware of any pop-up blockers** in your browser that may prevent downloading your application.
 - f. To **access a submission that you have previously saved**, click on the My Applications link in upper right and click the green Continue button on the application you wish to edit.
6. Once all tasks are completed, click the green Submit button **to submit**.
 - a. If the button is grayed out, it means your submission is not yet complete; please be sure all required fields and uploads are complete within each task and that you have clicked the Mark as Complete button within each task.
 - b. Review your submission in the window (or in the PDF that you have downloaded- see 5e). If you want to make changes, navigate back to your application and reopen/edit any tasks that need editing. **You can download your submission as a PDF (instructions above in 5e) to review your response(s) before clicking submit.**
 - c. Once you are **ready to submit**, click the green Submit Your Application button on the left side of the window. You will need to confirm your submission by clicking the green Submit button in the pop up window. **Once your responses have been**

submitted, it cannot be edited. Please be sure that your responses are complete BEFORE submitting. If you inadvertently submit and it is before the deadline, please contact rareasone@chanzuckerberg.com.

7. After submission, you will **receive an auto-email** within a few minutes. If you do not receive a confirmation email within a few minutes, please check your spam folder. If you still have not received your confirmation email, please email rareasone@chanzuckerberg.com.
8. If you would like to view your submission after you have submitted it, it can be accessed through the My Applications link in the upper right corner.

The RFI Submission consists of the following sections (called “tasks” in the portal):

- **Submitter Information:** The information entered should be for the Submitter.
 - Name and email (auto-filled): To edit your name or email, please do so in your account information by clicking your name in the upper right corner and clicking My Account in the dropdown menu.
 - Role and/or background: check all that apply
 - Academic
 - Biotech or pharmaceutical industry
 - Clinician or healthcare provider
 - Data-related occupations (e.g., computational biologist, statistician, biostatistician, ML researcher, data scientist, data analyst, etc.)
 - Engineer or developer (e.g., health technology, software, data, etc.)
 - Ethicist or bioethicist
 - Health economist
 - Health policy
 - Government agency or regulator
 - Lawyer
 - Member-based organization (e.g., umbrella patient organizations)
 - Ontologist or standards developer
 - Patient or caregiver
 - Patient group
 - Researcher
 - Social scientist
 - Student or postdoc
 - Other: _____
 - Affiliations: List up to five organizational affiliations. To add another row, click the "Add another row" box.
 - Organization name
 - Type of Organization: Academic, Government, Company/Industry, Other nonprofit, Other
 - Country

- Where do you work and/or where are you based? List up to 10 countries. To add another row, click the "Add another row" box.
 - Country
 - State/Province: Enter n/a, if not applicable.
 - Disease Area: Describe any rare diseases or disease area you work with or are affiliated with (maximum of 25 words).
 - LinkedIn, Twitter, website, online profile, etc.: Provide the links to your LinkedIn, Twitter, or other website profiles (optional). Provide any additional online profiles (optional; up to three). Where a URL is requested, please use the format <https://example.com>.
- **Equal Opportunity & Diversity (optional):** CZI Science supports the science and technology that will make it possible to cure, prevent, or manage all diseases by the end of this century. Everyone is affected by disease, yet different communities are affected by or experience disease in different ways. Moreover, due to systemic barriers, the scientific enterprise itself is not a place where all voices and talents thrive. We believe the strongest scientific teams—encompassing ourselves, our grantees, and our partners—incorporate a wide range of backgrounds, lived experiences, and perspectives that guide them to the most important unsolved problems. To enable our work, we incorporate diverse perspectives into our strategy and processes, and we also seek to empower community partners to engage in science.

We request demographic information associated with submissions in response to CZI's Requests for Information (RFI). This information helps us learn from the RFI process, as well as improve our strategies to help ensure people who identify as members of underrepresented or marginalized groups in science are aware of and able to submit information that can shape CZI's strategies. Please note that answering the questions below is **voluntary**, and demographic information will not be used to evaluate the submitted responses or to make any future funding decisions. Responses will be shared only with limited personnel, who will use that information only for the purposes described in this paragraph.

The information below may be entered for the Submitter.

- What is your race/ethnicity? (optional)
- What is your gender? (optional)
- Are you transgender? (optional)
- Are you a member of the LGBTQ community? (optional)
- Do you have one or more disabilities? Please specify (optional)

If you have any additional questions about why we ask this, what we do with the data, or to share suggestions for improvement, please reach out to rareason@chanzuckerberg.com.

- **RFI Questions & Prompts**

Through this Request for Information (RFI), we aim to learn more about a particularly vast and complex challenge that many patient communities experience when leading or co-designing efforts to collect and share data: **the lack of interoperability**. For an

overview or more details on the RFI, please refer to the [RFI page](#).

We've provided six RFI questions below, each illustrating a different type of challenge or barrier that can impede registry data interoperability or hinder better usability and analyses across data sources.

Please note, **you are welcome to respond to any number of these questions that you wish to answer**. You are also welcome to provide more than one response to a given question or to come up with your own prompt and describe a challenge or barrier that's not reflected in any of the RFI questions. You may input up to 10 responses.

We use the term "challenge" broadly—you can describe, for example, technological barriers, functional limitations, administrative burdens, ethical concerns, cultural or societal concerns, legal or policy issues, lack of capacity or resources, among others.

Each response can be up to 200 words, but we highly encourage concise responses.

1. **Data capture and collection:** What are the challenges for patients or clinicians in accessing data from electronic health records (EHRs) to share with a registry or research study, such as inconsistencies in EHR formats?
2. **Data standardization:** What are the challenges for collaborators in agreeing on critical data elements, clinical nomenclature, biomarkers, or key outcome measures to improve clinical care and accelerate therapeutic development?
3. **Data application:** What are the challenges for academic and industry researchers in accessing, querying, and analyzing data from registries, such as a lack of transparency on what data is available or restrictions on data use?
4. **Data reliability:** What are the challenges for patient groups in ensuring that their registries meet the data requirements of regulators (e.g., FDA or EMA) and their therapeutic approval processes, such as "clinically validated" or "regulatory grade" data?
5. **Data centralization and federation:** What are the challenges in integrating or aggregating data, including different data types, or querying across multiple data sources, whether that involves data related to the same disease, disease family, or data across multiple diseases?
6. **Data privacy and security:** What are the challenges in sharing data more broadly while protecting privacy, security, and individual consent, such as limitations in current data sharing platforms or different interpretations of HIPAA and GDPR obligations?
7. *Create your own prompt, or describe a challenge or barrier that's not reflected in any of the above RFI questions. We want to hear your thoughts!*

- For each prompt you wish to respond to (up to 10):
 - Provide a response (maximum of 200 words). Concise responses are encouraged.
 - How would you categorize the challenge(s) or barrier(s) you described? Check all that apply:
 - Administrative burden
 - Cultural or societal concern
 - Ethical concern
 - Legal or policy issue (e.g., privacy or governance),
 - Lack of capacity or resources
 - Technological barrier or functional limitation
 - Other
 - OPTIONAL: Propose any ideas for potential solutions or suggest organizations, projects, or actors that might be uniquely suited to address the challenge or barrier you've described. You can name ideas, people, or institutions across diverse fields or expertise, and you're welcome to name yourself and/or your affiliates. (maximum of 200 words)

- Final Thoughts:
 - We want to hear any thoughts, comments, or feedback you may have, whether about the RFI itself or any additional information you'd like to share. (maximum of 200 words)
 - Please upload any documents relevant to the RFI that you would like to share (up to three files). (maximum file size 20 MB)
 - Add a description about your uploads (maximum of 100 words)

QUESTIONS?

For administrative and programmatic inquiries pertaining to this RFI, please contact rareasone@chanzuckerberg.com with the **subject line: RAO RFI**. For technical assistance with SMAppl, please contact support@smapply.io or while logged into SMAppl, click on the information "i" link in the upper right corner and submit a help request ticket.