UsAgainstAlzheimer's

# Responses to RFI Questions
# Alzheimer's Disease Evidence Accelerator
**June 3, 2022**

**Can data contributors (e.g., RWD companies) access data from ADEA that they did not contribute? If so, what data and how?**

UsAgainstAlzheimer's is establishing a Design Steering Committee that will develop a governance structure for ADEA that includes principles for data access. We want ADEA to be a tool that drives learning across the Alzheimer's community while striking a balance of protecting proprietary data. The intent is to develop data access policies that will enable data contributors, as well as other stakeholders, broad access to data to address important questions, with appropriate measures to ensure privacy and appropriate use.

**What are the data access and/or data use case implications of the ADEA being a 'pre-competitive' environment?**

In general, a 'pre-competitive' environment such as the one envisioned by ADEA allows stakeholders to collaborate on topics, problems, or questions of common interest and move forward together to the benefit of all involved and those affected by the collaboration and to divide-up any resource requirements among the participants effectively multiplying the investment by any one participant. For ADEA in particular, one of the biggest benefits besides resource sharing is the generation of a much larger set of data than likely could have been obtained by any single organization.

As for the specifics around data access or data use case implications, the answer will depend on the business model and data access/use licensing model adopted by ADEA. The pre-competitive model also means that policies for data access and data use cases will be developed through consultation with the collaborators themselves. The Design Steering Committee will work with the ADEA partners and members to decide the best model that best benefits Alzheimer's research and patients, while protecting patient confidentiality.

As a pre-competitive partnership, ADEA will operate in strict compliance with antitrust laws. In particular, nothing discussed at any ADEA meeting will touch upon any agreement on price, exclusion of suppliers from any market, or other restraint of competition. Those participating in any ADEA meeting will be strictly instructed to avoid discussion of competitively sensitive subjects, including costs, prices, sales, product marketing, and other confidential information.

**Is there a preliminary perspective on the target number of data partners per data type for the ADEA (e.g., target number of registries to partner with, claims databases, EHR aggregators)?**

The vision for ADEA is that it breaks down as many siloes as possible, that its umbrella is as comprehensive as possible. Prior to launching ADEA, we intend to have data from at least two partners as a proof of concept for conducting analysis across multiple data sources. Ideally, these

would be two different types of data sources (e.g., a registry and a claims database) to better inform the development of the platform capabilities. ADEA should be built to allow for the addition of data sources over time, however no specific target has yet been set.

**Please confirm that the ADEA is focused on U.S. data solely.**

The current scope of ADEA is with U.S. data only. In the future, ADEA may be expanded to countries outside the U.S. but this is currently out of scope for this RFI.

**What data format standards are under consideration / would be accepted for data sources that are brought into the ADEA (e.g., OMOP, SDTM)?**

One of the goals of this RFI process is to get insights into how to best implement ADEA. As such, the team will be looking for respondents to propose data format standards which they believe would best support this project. Also due to the likelihood that many sources of data contributed to ADEA may be stored in different formats, it will be helpful for respondents to explain their approach to potentially converting the native data formats to the data format standard(s) eventually adopted by ADEA. Ultimately, the data format standard(s) adopted by ADEA will be decided by the Design Steering Committee based upon the recommendations by our data partners.

**What timeline does the team have for specific components of the ADEA including creating the coordinating center, establishing the UsA2 registry, and bringing in existing real-world data partners?**

The initial focus will be on selecting partners to support the ADEA coordinating center and beginning work with at least two real-world data partners, which we would anticipate in Q3/Q4 of 2022. Development of the UsA2 registry would begin soon after the selection of the coordinating center vendor and would be occur in parallel with development of the main ADEA platform.

**Can you provide any further information on which elements of the system are priorities for expedited implementation?**

See response to previous question.

**What are requirements for the structure of the RFI response (e.g., must include proposed timeline for collaboration)?**

RFI responses should not exceed 10 single-sided pages (single-spaced, 12-point font minimum). Brevity and structured format, such as bulleted items, are encouraged. We also strongly encourage respondents to address the questions written in bold italics throughout the RFI. It would be helpful for respondents to discuss timeline considerations for their organization in the RFI response.

**Who would be responsible for recruiting and engaging with the RWD partners, existing registries, and RWE data holders? Would this be the coordinating center, the steering committee, or someone else?**

The initial thought is that the ADEA coordinating center would have primary responsibility for recruiting, engaging, and retaining the RWD data partners. They would be supported in the effort by UsAgainstAlzheimer's and the Steering Committee. If respondents envision significant barriers to this approach, they should propose an alternative in the RFI.

**Has a budget been proposed for design, development, and implementation of the ADEA? If so, can this be disclosed?**

One purpose of the RFI is to obtain initial cost estimates for the various components of the project to support these on-going fundraising discussions. We recognize that such an estimate would not constitute a formal proposal of the cost of services.

**Will UsA2 execute an NDA with my organization as part of the RFI process?**

UsA2 does not execute NDAs with organizations as part of the RFI process. As stated in Section 12.0 of the RFI - *Responses to RFI should contain only high-level discussions of product development efforts and should not contain trade secrets or confidential information. UsA2 does not make any confidentiality commitments with respect to RFI responses but agrees not to publicly distribute RFI responses outside of UsA2 or share RFI responses with other respondents.* As such, please do not include any confidential or proprietary information in your response. When the project enters the scoping phase, UsA2 will be willing execute an NDA at that time.

## UsAgainstAlzheimer's Registry

**What size of registry (i.e., number of patients) is UsA2 looking to create?**

We do not have a specific target size for the UsA2 registry at this time.

**What data elements from EHRs, unstructured narrative text, PROs, caregiver assessments, lab data, and/or imaging data is must-have for the registry? What data elements would be nice-to-have?**

We have not yet made final decisions about required or optional data elements for the ADEA. Given the type of clinical and research questions likely to emerge as important for all stakeholders, we anticipate prioritizing patient demographics, medication history, laboratory and imaging data, and measures of cognition, function, quality of life (patient and caregiver).

**What inclusion/exclusion criteria does the team plan for the registry? For example, can AD patients not currently eligible for mAb treatment enroll?**

The ADEA is intended to capture the widest possible range of patients with Alzheimer's disease, potentially including people who are at risk but currently not symptomatic, The capacity to address questions about anti-amyloid Ab treatments is an important objective, but not the only objective of this initiative. We are very much interested in collecting data from people on anti-amyloid monoclonal antibodies and those not on these treatments, whether or not they are currently eligible for treatment.

**What length of prospective / retrospective data is the team looking for?**

We have not yet determined the length of time needed for retrospective and prospective data. In general, at least a year of retrospective data is desirable, and we are hoping that the ADEA infrastructure will allow for a minimum of several years of prospective data. We will be interested in any suggestions from RFI respondents on this question.

**Is being able to direct physicians to perform clinician administered assessments a nice-to-have or a must-have?**

In order to minimize data collection burden to the greatest extent possible, we are particularly interested in focusing on assessments of patient cognition, function, and quality of life that do not require clinician-administered assessment tools. We also recognize that it will be necessary to have access to some clinician-administered assessments in order to validate information obtained directly from patients and caregivers.