Breakthrough Discoveries for thriving with Bipolar Disorder

Request for Applications (RFA): Integrated Network Mobile Application Partner

November 2024

KEY DATES	
RFA Released	November 7, 2024
Submission Deadline	January 10, 2025
Review Period and Finalist Interviews	January - February 2025
Projected Award Notification	Mid-February 2025
Project Start	March 2025

Opportunity Snapshot

Breakthrough Discoveries for thriving with Bipolar Disorder (BD²) seeks applications from qualified organizations or teams to develop and manage a comprehensive mobile application system for data collection, monitoring, and analysis for the Integrated Network. The Integrated Network is part of a multidisciplinary initiative to increase understanding of the heterogeneity, progression, and underlying biology of bipolar disorder and, ultimately, to identify novel strategies for improved care and intervention. The mobile application platform must incorporate both Ecological Momentary Assessment (EMA) tools and passive data collection, support data security and integrity, and provide user-friendly dashboards for study staff and participants. The platform must be compatible with both iOS and Android devices. BD² plans to award up to $1.35 million USD over five years to the successful applicant.

APPLY HERE

About BD²

Bipolar disorder is a highly complex and heterogeneous disorder that is often debilitating. Even though it is prevalent in approximately 3% of individuals worldwide and is recognized as a leading cause of disability, little is known about its biology. Advancements in our understanding and treatment of bipolar disorder to date remain far from ensuring that everyone living with it can manage their condition and lead independent, fulfilling lives.

BD² is the first organization focused on funding and advancing research and care for bipolar disorder on a global scale. Our collaborative, open-science approach is intentionally designed to transform and shorten the time it takes for scientific breakthroughs to make a meaningful difference in the lives of the tens of millions of people with bipolar disorder. For too long, there have been limited advances in the study and treatment of bipolar disorder due to a lack of collaboration and funding. It's time for a new approach.

About the BD² Integrated Network

The purpose of the Integrated Network is to improve the health and well-being of people living with bipolar disorder by engaging a network of collaborating investigators and clinicians to:

i) build an unprecedented data ecosystem for bipolar disorder comprised of longitudinal clinical and biological data

ii) implement and inform data-driven improvements in care

iii) generate novel insights for interventional approaches

In partnership with people living with bipolar disorder, clinicians, and researchers, BD² established the Integrated Network to accelerate research and dramatically improve systems of care for bipolar disorder. It embraces a two-pronged approach: a traditional Longitudinal Cohort Study designed to generate in-depth phenotypes of bipolar disorder over time and a Learning Health Network aimed to iteratively improve outcomes.

The Longitudinal Cohort Study (LCS)

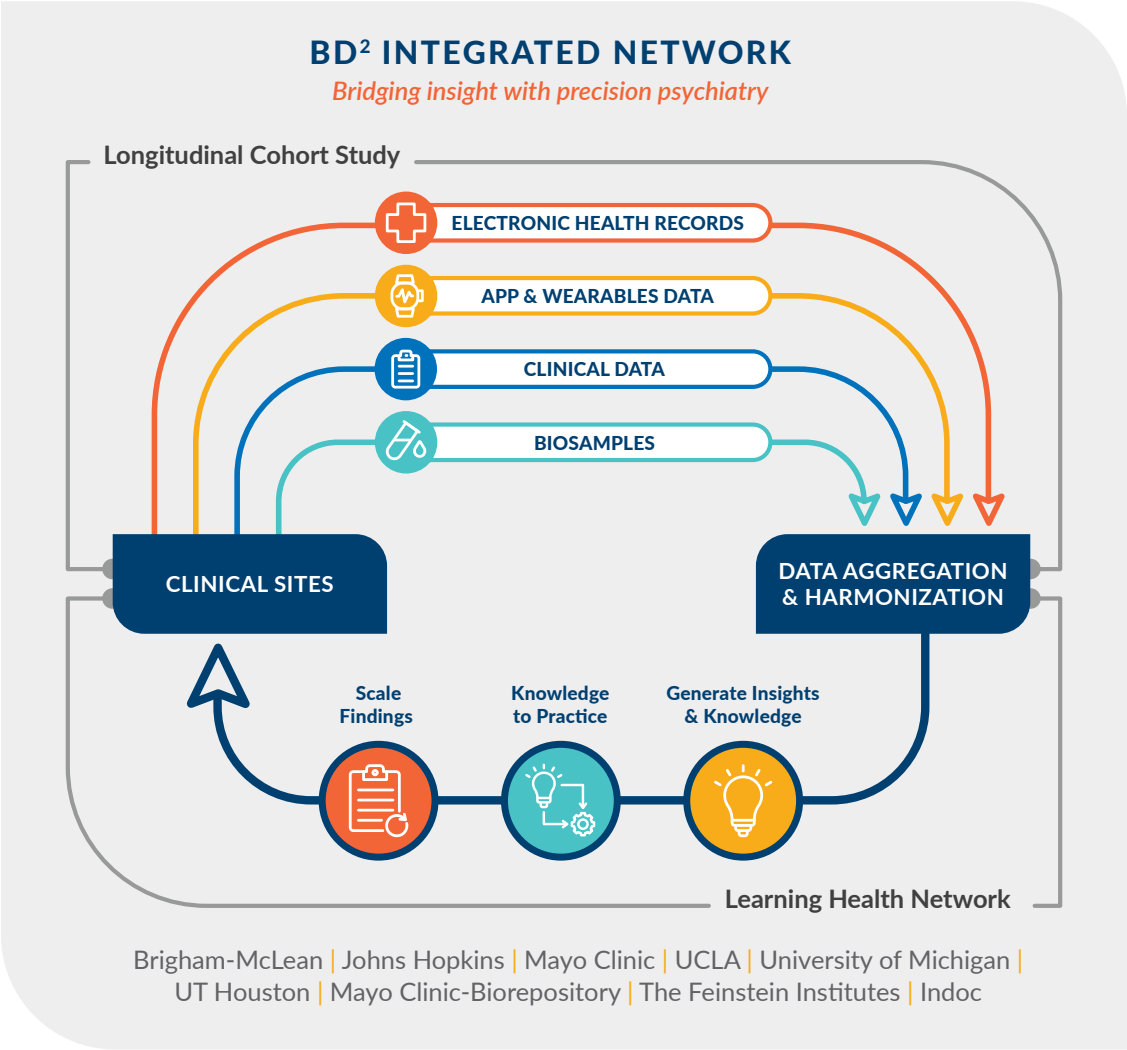
The Integrated Network is conducting deep phenotyping of a diverse group of people with bipolar I disorder to accurately capture the trajectory of the disease and to clarify its underlying biology. This will enable the identification of key clinical (e.g., recurrence rate, comorbid diagnoses, early life adversity, sleep disruption, cardiovascular risk), neural (e.g., structural changes in gray matter, white matter disease, cognitive deficits), and biological (e.g., inflammation, elevated stress hormones, genomics) processes that drive outcomes in bipolar disorder. The overall goal is to recruit and retain 4,000 participants with bipolar I disorder across 15 unique study sites.

The Learning Health Network (LHN)

At each study site, a core team of clinicians will carry out best clinical practices with their patients and learn from other teams within the network to augment their care through evidence-based approaches. These clinicians, with local IT support, will be champions of the LHN within their institution and work to implement on-the-ground, near-real-time improvements in clinical care based on emerging insights generated from network data.

Coupling an LCS with an LHN links discovery research with improvement of clinical care, so insights from basic science research and clinical practice inform improvement targets and health outcomes goals—ultimately increasing the health of people with bipolar disorder (Figure 1).

Figure 1. Overview of the BD² Integrated Network. The BD² Integrated Network brings together research and care in a unique way that sets the stage for personalized care. The ultimate model of change will come from combining these data streams and processes in novel ways. Through the Learning Health Network, we will intentionally facilitate the application of findings from the Longitudinal Cohort Study data to care settings.



Centralized Service

A foundational characteristic of this initiative is the use of centralized service providers. This includes a Clinical Coordinating Center (CCC) and a Data Coordination Center (DCC). These providers standardize clinical and data processes, including administration of psychological assessments as well as data capture and distribution. Personnel from the centralized service teams will work closely with the application service provider to ensure successful integration into the study.

The Clinical Coordinating Center

The CCC, led by the Feinstein Institutes for Medical Research, is managed by a team of bipolar disorder clinicians and care providers. The CCC team coordinates the central IRB approval and works with each study site to obtain local IRB ceding approval. Members of the CCC team perform a variety of clinical assessments, including structured interview-based validation of the bipolar I diagnosis and comorbid psychiatric diagnoses, mood symptom ratings, sleep surveys, and more. Centralizing these services allows for improved standardization of the assessments.

The Data Coordination Center

The DCC and the Central Data Repository (CDR) are both managed by Indoc. The DCC is responsible for supporting program data standardization and harmonization efforts, as well as aggregating and integrating data that are collected across sites and modalities. The DCC-operated BD² Pilot Data Platform (Indoc Pilot Platform) will house clinical data (including data derived from the app), biosample data, neuroimaging data, and mobile health data collected from study participants. The app service provider will send data directly to the BD² Pilot Data Platform. Data scientists will work with the app service provider to ensure that incoming data are correctly standardized, packaged, and meet the initiative's criteria.

Funding

BD² will award the successful applicant up to $1,350,000 (USD) over five years to administer the app to 600 participants of the Integrated Network. This includes costs to deploy app-based collection of the required data modalities, data monitoring, processing, and analysis. The anticipated award date is approximately mid-February with a projected start date in March and expectation for first participant enrolled by the end of April 2025.

Organizational Eligibility

Proposals will be accepted from any public or private-sector organization, including non-profit and for-profit organizations.

Organizations with prior experience working with longitudinal research studies, specifically in the psychiatric space, are encouraged to apply.

Scope of Work

BD² seeks a service provider to provide a mobile application platform to support a large-scale, global clinical research study. The platform should facilitate both Ecological Momentary Assessment (EMA) and passive data collection, while ensuring secure data storage, supporting robust data analysis, and providing user-friendly monitoring dashboards for study staff and participants. The system must comply with privacy regulations and be compatible with both iOS and Android platforms to support the study's "bring your own device" design.

Ecological Momentary Assessment (EMA) Administration

The application must integrate the following EMA tools:

- PHQ9 (Patient Health Questionnaire)
- PMQ (Perceived Motivational Questionnaire)
- DUSI (Drug Use Screening Inventory)
- EDS (Ehlers-Danlos Syndrome)
- WHO-5 (World Health Organization Well-being Index)
- GAD7 (Generalized Anxiety Disorder Assessment)
- AUDIT (Alcohol Use Disorders Identification Test)

Specific EMA Functional Requirements:

- **Customizable survey frequency:** Enable the study team to schedule EMA assessments at specific times or intervals and adjust based on participant availability.
- **Reminder system:** Integrate automatic push notifications and reminders to prompt participants to complete the assessments.
- **Data synchronization:** Ensure that responses are collected in real time and stored securely, with immediate data transmission to the cloud.
- **Skip logic and branching:** Enable dynamic survey structures where responses to certain questions trigger or skip others.

Passive Data Collection

The platform must collect passive data from participants' mobile devices, specifically focusing on:

- **Accelerometer:** Continuous tracking of physical activity and movement patterns (e.g., steps, intensity). Provide a complete list of available measures.
- **GPS:** Location tracking with privacy-preserving obfuscation to ensure participant anonymity while maintaining relevant location-based data.
- **Screen-time usage:** Measure and analyze participants' daily screen usage (time spent on different apps, phone unlocks).

Additional Passive Data Collection Requirements:

- **Low-power mode:** Ensure that passive data collection does not significantly drain battery life.
- **Disruption handling:** Automatically handle disruptions in data collection due to phone restarts, software crashes, or signal loss.
- **Data buffering:** Enable the system to buffer passive data during periods without internet connection and upload data once a connection is reestablished.
- **Privacy compliance:** Implement data anonymization techniques to prevent sensitive information leakage while still allowing for useful insights.

Voice Biomarker Collection (Optional)

Applications that include the collection of voice data are encouraged. These data will be used to analyze biomarkers that could indicate depression or mania.

Voice Biomarker Collection Requirements:

- **Voice recording:** The application must support periodic or triggered voice recordings from participants, which can be analyzed for acoustic features such as pitch, tone, rhythm, and speech rate.
- **Acoustic feature extraction:** The platform must automatically extract and process key acoustic features (e.g., tone variability, pauses, speech rate, intonation, energy levels) relevant for detecting voice biomarkers related to mental health conditions (e.g., depression, anxiety, mania).
- **Natural Language Processing (NLP) integration:** Provide the option to integrate NLP-based models that can analyze not only acoustic features but also linguistic content for further health insights.

- **Privacy and consent management:** Ensure secure handling of voice data, with explicit consent processes for voice recording, storage, and analysis. Participants must have the option to review, opt out of, or delete recordings.
- **Real-time processing:** Enable the platform to process voice recordings in real time, either locally on the device or through secure cloud-based servers, and provide feedback to participants or researchers (if applicable).
- **Compression and storage:** Implement voice data compression techniques to minimize storage needs without compromising audio quality and ensure that voice data are stored securely with appropriate encryption.
- **Noise management and quality control:** Ensure that voice recordings are of sufficient quality for analysis, with features for noise reduction and feedback mechanisms for participants to ensure clarity in recordings.

Voice Biomarker Collection in Clinical Validation:

- The platform should allow integration with voice biomarker research tools to ensure that voice data can be clinically validated for use in identifying and monitoring bipolar disorder.
- Provide options for longitudinal voice analysis to track changes in biomarkers over time and correlate them with other health outcomes.

Data Monitoring and Reporting Dashboards

Develop intuitive dashboards to support real-time data monitoring and reporting for both study **site staff** and **participants**.

- **Study Staff Dashboards:**
  - **Real-time participant monitoring:** Provide a clear and organized view of participant activity, showing EMA completion rates, passive data collection status, and engagement trends.
  - **Alerts and notifications:** Create a system for flagging participants who are inactive or experiencing technical issues with data collection.
  - **Data export functionality:** Enable the study team to export data in multiple formats (CSV, JSON, etc.) for further analysis in statistical software (e.g., SPSS, SAS, R). Have ability to export single participant data or data from groups of selected participants.
  - **Custom report generation:** Allow for the creation of customized reports that can be tailored to specific study needs (e.g., daily summaries, participant comparisons).
- **Participant Dashboards:**
  - **Progress tracking:** Provide participants with visual feedback on their study participation, showing completion rates for surveys and passive data contributions.
  - **Engagement features:** Offer motivational messages, badges, or progress bars to encourage continued participation.
  - **Personal insights:** Offer optional personal data summaries, showing trends in activity, mood, or behaviors based on their input, passive data and data stream to be received from the DCC of other key outcome measures.

Additional Dashboard Requirements:

- **Role-based access controls:** Ensure appropriate levels of access for different user roles (e.g., study coordinators, data analysts, participants).
- **Responsive design:** Ensure the dashboards are responsive and accessible across various devices (mobile, tablet, desktop).
- **Customization:** Dashboards should be customizable to reflect specific study branding (e.g., BD^2 branding) and layout preferences.

Responsible Data Storage and Management

- **Secure cloud storage:** All collected data should be encrypted at rest and stored on a secure, scalable cloud infrastructure (compliant with **HIPAA**, **GDPR**, or relevant regulatory frameworks).
- **Data encryption:** Use end-to-end encryption during data transmission and storage.
- **Automated backup:** Ensure regular automated backups of all collected data with minimal risk of data loss.
- **Data transfer:** Establish efficient pipelines for **secure and fast bulk transfer** of data to the study's DCC at regular intervals. This should include primary data collected, as well as applicable metadata, ideally any QC or flagging data resulting from implemented data processing and QC pipelines (see below).
- **Data access controls:** Implement strict access control measures to ensure that only authorized personnel can access or modify participant data.

Data Processing, Quality Control (QC), and Analysis

- **Automated data cleaning:** The platform must automatically clean and pre-process incoming data, identifying and flagging outliers, missing data, and inconsistencies.
- **Quality control (QC):** Implement QC processes that ensure data accuracy, completeness, and consistency across both EMA responses and passive data streams.
- **Dealing with missing data:** Implement strategies to manage and account for missing or incomplete data, both in EMA and passive data collection (e.g., imputation methods).
- **Data analysis pipelines:** Integrate with the study's analysis workflows, supporting both real-time and retrospective data analysis.

iOS and Android Compatibility

- The mobile platform must be compatible with the latest versions of **iOS and Android**, as well as prior versions (supporting at least 3-5 years of OS releases).
- **Broad device support:** The system should be tested on a variety of phone models to ensure cross-device compatibility and user experience consistency.
- **Device-specific optimizations:** Ensure that any platform-specific features (e.g., iOS location services and Android background data collection) are handled appropriately to avoid discrepancies.

Application Requirements

The application for this funding opportunity has two stages: i) a written proposal and ii) a finalist candidate interview.

Stage 1: Written Proposal Submission Guidelines

Interested applicants should complete the application through the online portal: HERE. The proposal should provide the following:

- Comprehensive technical proposal addressing all key requirements as outlined in the scope of work
- Detailed response to the prompts and questions outlined below
- Detailed project plan with milestones, timeline, and deliverables
- Budget estimates, including the cost of customization and ongoing support
- Case studies of previous work in voice biomarker collection, mobile health, or clinical trials

Application Prompts & Questions:

The written proposal assesses the applicant's suitability to partner with the Integrated Network and consists of a series of short answer questions and prompts, as outlined below. Please keep all answers to 250 words or fewer unless otherwise indicated.

V3 Framework Adherence

1. Alignment to the verification, analytical validation and clinical validation (V3) framework standards as outlined here. (500-word limit)

Analytical Validation

2. How will the platform validate the accuracy and reliability of sleep, movement, and if applicable, voice biomarker collection across different devices and conditions?
3. What steps will be taken to ensure reliable collection of both acoustic and linguistic data?

Signal Verification

4. How will the platform handle poor-quality voice recordings (e.g., background noise, interruptions)?
5. What methods are in place for handling missing data or disruptions in passive data collection?

Clinical Validation

6. Have any aspects of voice biomarker collection been clinically validated in other studies? The application portal will provide a space for uploading relevant materials.
7. Optional: How will the platform enable the use of collected voice data for clinical research and mental health assessments?

Training Materials for Study Staff

8. Please provide example training materials for study staff on how to use the voice biomarker features, including best practices for collecting high-quality voice recordings. The application portal will provide a space for uploading relevant materials.

Flexibility in User Interface (UI) Design

9. Describe your platform's flexibility in incorporating **BD² branding** and other design modifications. What are the lead time and costs associated with customizing the voice biomarker collection interface?

Solutions for Participant Engagement and Monitoring

10. How will the platform keep participants engaged in completing voice recordings and EMAs regularly?
11. Describe strategies for dealing with participant fatigue or disengagement during voice data collection.

Organizational Profile, Staffing & Team Composition

12. Provide a general overview of the organization including team size, number of years in business, number of studies completed with data delivered, number of clients, and annual revenues.
13. Outline the team's expertise in voice biomarker analysis, data security, and mobile app development for healthcare applications. (500-word limit)

Budget

Each applicant may request up to $1,350,000 (USD) for use over five years to provide services, as described in the scope of work above, to the Integrated Network and an initial cohort of 600 participants. The budget should clearly outline the costs associated with each aspect of the platform's development, deployment, and maintenance, ensuring that all key requirements are adequately funded.

The application portal will provide a space for uploading of a proposed comprehensive budget document. *Please break down the budget into the following categories, providing a justification for each listed cost:*

1. Personnel Costs

This section should outline the costs associated with the personnel involved in the design, development, and ongoing support of the platform. The budget should include:

- **Salaries:** Include for all key personnel, including developers, data scientists, project managers, and quality control specialists.
- **Consultant fees:** If you plan to use external consultants, include their fees, a detailed description of their role, and hourly or project-based rates.
- **Fringe benefits:** Include the percentage used to calculate fringe benefits, such as healthcare, retirement, or other employee benefits, if applicable.

Provide a detailed list of personnel, their roles, and the number of hours or percentage of their time dedicated to the project.

2. Software Development Costs

Include all costs related to the development of the mobile application and data management platform, including:

- **Front-end and back-end development:** Include costs for developing user interfaces, integrating survey/EMA tools, passive data collection sensors, and voice biomarker technology.

- **Third-party software licensing:** If any third-party software tools, libraries, or APIs will be used (e.g., voice biomarker analysis tools, NLP frameworks), include their licensing costs.
- **Mobile platform compatibility:** Include costs associated with ensuring the platform functions seamlessly across both iOS and Android, including device testing.
- **Customization and UI branding:** Include costs for custom branding, including BD^2 branding or study-specific modifications.

3. **Data Security and Compliance**

Costs for implementing security protocols and ensuring compliance with HIPAA, GDPR, and other relevant data privacy regulations should be included in the following categories:

- **Encryption technology:** Include costs associated with developing or acquiring encryption tools for data storage and transmission (e.g., end-to-end encryption).
- **Secure cloud storage:** Include recurring costs for secure cloud storage services (e.g., AWS, Google Cloud, Azure) used for data storage and backups.
- **Data privacy audits and certifications:** If third-party audits or certifications (e.g., HIPAA compliance certification) are required, include those costs.

4. **Data Management and Analytics**

Include costs related to the management, cleaning, processing, analysis visualization and transfer of data collected through the app:

- **Data processing pipelines:** Include costs related to the development of automated data pipelines for cleaning, processing, and analysis of EMA, passive sensor, and voice biomarker data.
- **Data transfer to Data Coordinating Center (DCC):** Include costs for preparing and processing data for transfer to the DCC.
- **Quality control (QC) and assurance:** Include costs for tools or services that will ensure data quality, handle missing data, and manage discrepancies in collected data.
- **Data reporting and dashboards:** Include costs associated with developing real-time dashboards for both study staff and participants, including features for monitoring and engagement, enabling mechanisms and processes to accept regular data transfers of key outcome measures from the DCC for visualizations in participant dashboards.
- **Data transfer:** Include costs associated with supporting regular bulk data transfers to the DCC.

5. **Maintenance and Technical Support**

Include all ongoing costs related to the maintenance and support of the platform post-deployment:

- **Bug fixes and updates:** Include costs for fixing bugs, implementing updates, and ensuring compatibility with future versions of iOS and Android.
- **Helpdesk or technical support:** Include ongoing costs for providing technical support to study participants and research staff, including staffing, software tools, or support contracts. Also, include a description of the system that will be used to provide these services (chat bot, ticketing etc.).
- **Server and hosting fees:** Include recurring costs for hosting the platform on secure servers or cloud infrastructure.
- **Data storage:** Include costs associated with storing study data.

6. **Training and Documentation**

Provide a budget for training materials and documentation, including costs associated with onboarding study staff and participants:

- **Training materials:** Include costs for developing user manuals, video tutorials, and in-person or virtual training sessions for site study staff on using the platform.
- **Documentation:** Include costs for creating comprehensive technical and operational documentation for the study team, including system architecture, data processing workflows, and data privacy practices.

7. **Participant Engagement and Retention**

Include costs for ensuring participant engagement throughout the study, such as:

- **In-app engagement tools:** Include costs associated with developing participant engagement features, such as notifications, feedback loops, rewards, and badges.
- **Engagement analysis:** Include costs for monitoring participant adherence and analyzing engagement trends over time, including tools or services for tracking participant dropout or disengagement.

Estimated costs for ongoing enrollment: Provide per-participant costs for enrollment beyond the 600 study participants included in this scope of work.

Budget Justification: For each category, provide a detailed justification for the proposed costs. Explain why each cost is necessary and how it contributes to the successful completion of the project. This is especially important for personnel costs, software licensing, data storage, and participant engagement costs.

Stage 2: Initial Review & Finalist Site Interviews

Written proposals will be reviewed by the BD^2 Leadership Team, BD^2 Scientific Steering Committee (SSC), members of the centralized service provider teams, as well as additional experts and stakeholders within the field of bipolar disorder. Proposals will be evaluated based on the responses to all requirements in this RFA. Following an initial review of the written proposals, a subset of applicants will proceed to the final review stage, consisting of an interview with the applicant team. Members of the BD^2 Leadership Team and additional reviewers will meet virtually with the applicant to further assess their ability to contribute to the Integrated Network and its goals.

Final Selection

Following proposal review and finalist interviews, the BD^2 Leadership Team and SSC will convene to select the successful applicant. The evaluation of an organization's ability to contribute to the Integrated Network will be based on the written material submitted, interviews, and, if requested, presentations. The successful applicant will be notified, and the BD^2 Leadership Team and members of the centralized service provider teams will work with the selected organization to begin onboarding.

Evaluation and Monitoring

Once the organization is funded and the application is implemented, progress reporting and assessments will be required. Members of the BD^2 Leadership Team will perform a formal review as often as every six months.

Funding Awarded at BD²'s Discretion

Responding to this RFA and/or submitting an application does not entitle any individual or organization to receive funding from BD². Funding, if any, would be provided in BD²'s sole discretion pursuant to the terms of a written agreement executed by BD² and the selected organization, the terms of which BD² may require to be acknowledged by the awardee.

Contact Information

An automated email confirmation is generated upon application submission. If you do not receive confirmation within 24 hours of submitting your application, please check your spam filters and then contact integratednetwork@bipolardiscoveries.org.

For inquiries about scientific priorities, eligibility requirements, and application submission, please contact integratednetwork@bipolardiscoveries.org. For all other questions, including general and media inquiries related to BD², please contact: info@bipolardiscoveries.org