Accelerating Medicines Partnership®
Schizophrenia
(AMP® SCZ)
Welcome and Overview of AMP
Schizophrenia

Joshua A. Gordon, M.D., Ph.D.
NIMH Director

Accelerating Medicines Partnership Symposium
February 6, 2024

Follow me on X: @NIMHDirector
Schizophrenia is a Leading Cause of Disability and Requires Early Intervention

- One of the leading causes of disability worldwide

- Early onset of symptoms (usually start between ages 16 and 30) and the long-lasting trajectory of this condition exacerbate both the impact and need

- Currently an unmet need for medications to address the disabling negative and cognitive symptoms

Global disability-adjusted life years (DALYs) rate per 100,000 by age group and gender

He et al., Epidemiology and Psychiatric Science, 2020
Schizophrenia: Aiming for Recovery

Adapted from Lieberman and First, *New England Journal of Medicine*, 2018
FNIH Led a 12-month Effort to Design a New AMP Partnership in Schizophrenia

Research strategy and planning involved 58 scientists from NIMH, FDA, 16 private-sector partners, and leading academic research institutions.

Private sector partners leveraged $99.38M in NIMH funding/5 years for the AMP SCZ initiative:
- RFA-MH-20-340, Clinical High Risk for Psychosis Research Network (U01)
- RFA-MH-20-341, Clinical High Risk for Psychosis: Data Processing, Analysis, and Coordination Center (U24)

Private partners contributed $18.33M+/5 years:
- 3 industry partners
- 1 private foundation
- 4 non-profit partners
AMP SCZ Overview

AMP SCZ is a large, international collaboration focused on developing and implementing a set of tools to create multimodal algorithms that distinguish trajectories and endpoints in individuals at clinical high-risk for psychosis (CHR) – conversion, remission, and unremitted symptoms.

**Aim 1:** Provide tools to enable the selection of enriched patient populations, to considerably improve success in developing pharmacologic treatments for patients with CHR for psychosis

**Aim 2:** Develop and validate biomarkers and outcome measures that can establish early indicators of pharmacologic treatment efficacy
AMP SCZ Project Timeline

Observational Study

- Protocol Harmonization
- IRB Submissions
- SOP Development
- Data Transfer Pipelines Creation

Observational Study Enrollment Launch

December 2022 RFI was released Requesting Response for Candidate Phase 2 Ready Compounds

July 2023 Notice of PoP Funding Opportunity was Issued

July 2024 PoP Trial

June 2025 Observational Study Grant Year 5 End Date

U24: Data Processing, Analysis, and Coordination Center (DPACC): Develop Data Flow Pipelines, Provide QA/QC, Analyze Data Sets

U01: CHR Research Networks: Trajectory and Predictors in the CHR for Psychosis Population: Prediction Scientific Global Consortium (PRESCIENT) and Psychosis Risk Outcomes Network (ProNET)

NIMH Data Archive (NDA): Stores the Data and Makes it Available to the Broader Research Community

U24: Clinical Trial Data Processing, Analysis and Coordination Center (DPACC) CHR Clinical Trial Sites

U01: CHR Clinical Trial Network
AMP SCZ: Observational Study
Harmonized Research Network & Data Processing, Analysis, and Coordination Center

Recruitment launched in Q2 2022
- CHR participants: 1,977
- Healthy control participants: 640

ProNET: Psychosis-Risk Outcomes Network
- Scott Woods
- Carrie Bearden
- John Kane
  
  Yale University
  University of Northwell Health
  California, Los Angeles

DPACC: Data Platform with Data Processing, Analysis, & Coordination Center
- Martha Shenton
- Rene Kahn
  
  Harvard University
  Icahn School of Medicine at Mount Sinai

PRESCIENT: Trajectories and Predictors in the Clinical High-Risk for Psychosis Population
- Barnaby Nelson
- Patrick McGorry
  
  University of Melbourne
AMP SCZ: Update on the Observational Study

- Clinical, cognitive, neuroimaging, EEG, genetics, fluid biomarkers, speech and facial expression, and daily digital assessments are collected in 1,977 CHR individuals and 640 healthy controls for up to two years.
- A total of 1,111 individuals (607 in ProNET, 504 in PRESCIENT) have been recruited into the study.
- An additional 217 individuals have consented and are being assessed for inclusion.
Next Phase: Proof of Principal Trials

Proof of principle trials will test the utility of tools and hypotheses

Budget to Test Two Compounds: ~ $21M/year in total costs for 5 years

**AMP SCZ Proof of Principle U24 and U01 RFAs**

- Accelerating Medicines Partnership Schizophrenia (AMP SCZ): Clinical High Risk for Psychosis Clinical Trial Network (RFA-MH-24-150)
- Single Source: Accelerating Medicines Partnership Schizophrenia (AMP SCZ: Clinical Trial Data Processing, Analysis, and Coordination Center (RFA-MH-24-151)
Thank you!

**PRESCIENT**
- Barnaby Nelson
- David Cotter
- David Clark
- Scott Clark
- James Scott
- Helen Zhou
- Kim Do
- Rachel Upthegrove
- Paul Amminger
- Mario Alvarez
- Elekta Papadopoulos
- Caroline Gao
- Inge Meurs
- Simon D’Alfonzo
- Hanneke Wardenaar-Wigman
- Dominic Dywer
- Merete Nordentoft
- Louise Birkedal Glenthaj
- Joseph Kambeitz
- Sophie Tod
- Philippe Conus
- Christina Phassouliotis
- Eric Yi Chen
- Swapna Kamal Verma
- Ivana Dzafic
- Ann Ee Ching

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- Martha E. Shenton
- Rene Kahn
- Justin Baker
- Sylvain Bouix
- Guillermo Cecchi
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- Michael Harms
- Tina Kapur
- Marek Kubicki
- Kathryn Eve Lewandowski
- Daniel Mathalon
- Johanna Seitl-Holland
- Robert Glynn
- Sero Nicholas
- Ofer Pasternak
- Russel Poldrack
- Pablo Polosecki
- Yogesh Ratik
- Abraham Reichenberg
- Jenna Reinen
- Inge Winter-Van Rossum
- Tashrif Billah
- Lisa Brown
- Eduardo Castro
- Justine Chen
- Kang Ik Kevin Cho
- Yoonho Chung
- Rastko Ciric
- Evan Gents
- Anastasia Haidar
- Grace Jacobs
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- Eric Lin
- Elise Blaeuae

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- Angela Nuhe
- Nicholas Breitborde
- Al Powers
- Brittany Quagan
- Susan Ray
- Marvin Ruan
- Gennarina Santorelli
- Zailyn Tamayo
- Steve Hyman
- Public & Private Partners
- Lymsey Bilsland
- Brandon Staglin
- Carlos Laurrau
- Gahan Pandina
- Michael Sand
- Sharon Roth
- Brian Johnso
- Ken Duckworth
- Nitin Gogtay
- Christoph von der Goltz
- Sri Gopal
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- Florence Butlen-Ducuing
- Diana Clark
- Sriniv Vaivan

**FNIH**
- Steve Hoffman
- Joseph Menetski
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- Sri R. Pullagura
- Jane Lin

**FDA**
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- Sara Shnider
Exploring Digital Assessment: Strategies and Implementation in AMP® SCZ

Justin Baker, MD PhD

Associate Professor of Psychiatry,
Harvard Medical School
Scientific Director, Institute for Technology in Psychiatry,
McLean Hospital
Disclosures

I have received consulting fees from **Verily Life Sciences, Inc.**, **Mindstrong Health, Inc.**, **Healios Limited, Inc.**, **Niraxx Therapeutics, Inc.**, **Sama Therapeutics, Inc.**, and **Tetricus Labs, Inc.**, for work unrelated to today’s presentation.

I have received grant funding from the NIMH, including U24MH124629 (PI: Martha Shenton & René Kahn; “**Psychosis Risk Evaluation, Data Integration and Computational Technologies (PREDICT): Data Processing, Analysis, and Coordination Center**”), which will be discussed here.
The AMP® Schizophrenia Project

Multimodal, Longitudinal Biobehavioral Assessment to Follow Psychosis Risk into Disease & Remission
**Digital Measures** have the potential to provide signals that:

- can be collected in **naturalistic contexts** while young people live their lives,
- are sensitive to **within-person** changes over time,
- may be useful in **early detection** of clinical changes,
- can **trigger just-in-time** interventions.
**Digital Assessment in AMP® Schizophrenia**

- **12-months of digital assessments** (Phone + Wearable) for CHR and Healthy Controls
- **Monthly Digital Check-Ins** with research staff coincide with structured clinical assessments

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
<th>Visit 6</th>
<th>Visit 7</th>
<th>Visit 8</th>
<th>Visit 9</th>
<th>Visit 10</th>
<th>Visit 11</th>
<th>Visit 12</th>
<th>Visit 13</th>
<th>Visit 14</th>
<th>Visit 15</th>
<th>Visit 16</th>
<th>Conversion</th>
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<tbody>
<tr>
<td>Month</td>
<td>-3 to -1</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
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<td>12</td>
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<td>Consent Form</td>
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<tr>
<td>Brief Psychiatric Rating Scale</td>
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<tr>
<td>Actigraphy (daily)</td>
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<tr>
<td>Digital Data (daily passive sensing, EMA, audio diary)</td>
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</tbody>
</table>

Accelerating Medicines Partnership®
SCHIZOPHRENIA
Digital Assessment in AMP® Schizophrenia

**Brief Psychiatric Rating Scale**

Zanello et al. 2013

BPRS is expected to vary across participants and within individual participants over time

- Total BPRS is a surrogate for overall clinical severity
- Data reduction methods (e.g., factor analysis) allow us to link variance in symptom domain severity with DHT-derived measures using multi-level models to identify within- and between-person relationships.
**Ecological Assessments:**

- 30 questions
- 8 languages
- Open-ended Voice Diary

**“How have things been going for you lately?”**

### Digital Assessment in AMP® Schizophrenia

Digital Measures using the MindLAMP Smartphone Platform and Axivity Wearable

---

<table>
<thead>
<tr>
<th>STEM FORMULATION</th>
<th>PROMPTS / OPTIONS</th>
</tr>
</thead>
</table>
| “Today I felt _____.” | 0. Not at all
| 1. Slightly
| 2. Somewhat
| 3. Quite a bit
| 4. Extremely |

<table>
<thead>
<tr>
<th>#</th>
<th>STEM SPECIFIER</th>
<th>CONSTRUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Energetic</td>
<td>Positive Valence / Arousal</td>
</tr>
<tr>
<td>2</td>
<td>Cheerful</td>
<td>Positive Valence / Arousal</td>
</tr>
<tr>
<td>3</td>
<td>Content</td>
<td>Positive Valence / Arousal</td>
</tr>
<tr>
<td>4</td>
<td>Relaxed</td>
<td>Positive Valence / Arousal</td>
</tr>
<tr>
<td>5</td>
<td>Enthusiastic</td>
<td>Positive Valence / Arousal</td>
</tr>
<tr>
<td>6</td>
<td>Down</td>
<td>Negative Valence / Arousal</td>
</tr>
<tr>
<td>7</td>
<td>Empty</td>
<td>Flat affect</td>
</tr>
<tr>
<td>8</td>
<td>Anxious</td>
<td>Negative Valence / Arousal</td>
</tr>
<tr>
<td>9</td>
<td>Stressed</td>
<td>Negative Valence / Arousal</td>
</tr>
<tr>
<td>10</td>
<td>Irritable</td>
<td>Negative Valence / Arousal</td>
</tr>
<tr>
<td>11</td>
<td>Worried</td>
<td>Negative Valence / Arousal</td>
</tr>
<tr>
<td>12</td>
<td>Lonely</td>
<td>Negative Valence / Arousal</td>
</tr>
<tr>
<td>13</td>
<td>Suspicious of others</td>
<td>Positive Symptoms</td>
</tr>
<tr>
<td>14</td>
<td>Very special</td>
<td>Positive Symptoms</td>
</tr>
<tr>
<td>15</td>
<td>Strange</td>
<td>Positive Symptoms</td>
</tr>
<tr>
<td>16</td>
<td>That others could read my thoughts</td>
<td>Positive Symptoms</td>
</tr>
<tr>
<td>17</td>
<td>That others could control me</td>
<td>Positive Symptoms</td>
</tr>
<tr>
<td>18</td>
<td>Like my thoughts felt confused or blocked</td>
<td>Disorganised thoughts</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STEM FORMULATION</th>
<th>PROMPTS / OPTIONS</th>
</tr>
</thead>
</table>
| “Today ________.” | 0. Strongly Disagree
| 1. Somewhat Disagree
| 2. Neutral
| 3. Somewhat Agree
| 4. Strongly Agree |

<table>
<thead>
<tr>
<th>#</th>
<th>STEM SPECIFIER</th>
<th>CONSTRUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>My thoughts were racing</td>
<td>Positive Symptoms</td>
</tr>
<tr>
<td>20</td>
<td>I saw things that others couldn’t see</td>
<td>Positive Symptoms</td>
</tr>
<tr>
<td>21</td>
<td>I heard things that others couldn’t hear</td>
<td>Positive Symptoms</td>
</tr>
<tr>
<td>22</td>
<td>I could concentrate well</td>
<td>Resilience</td>
</tr>
<tr>
<td>23</td>
<td>I could handle what came my way</td>
<td>Resilience</td>
</tr>
<tr>
<td>24</td>
<td>I could enjoy nice things when they happened</td>
<td>Anhedonia</td>
</tr>
<tr>
<td>25</td>
<td>I spent time with other people (live)</td>
<td></td>
</tr>
<tr>
<td>26</td>
<td>I spent time with other people (online/digitally)</td>
<td></td>
</tr>
<tr>
<td>27</td>
<td>I felt like undertaking something</td>
<td>Resilience</td>
</tr>
<tr>
<td>28</td>
<td>I was able to function well</td>
<td>Functional</td>
</tr>
<tr>
<td>29</td>
<td>I experienced a negative/unpleasant event</td>
<td>Events</td>
</tr>
<tr>
<td>30</td>
<td>I experienced a positive/pleasant event</td>
<td>Events</td>
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</tbody>
</table>
**Digital Assessment in AMP® Schizophrenia**

**Digital Measures using the MindLAMP Smartphone Platform and Axivity Wearable**

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<th>Ecological Assessments:</th>
<th>Digital Phenotyping:</th>
<th>AX3 Axivity Wearable:</th>
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<tbody>
<tr>
<td>• 30 questions</td>
<td>• Accelerometer</td>
<td>• Triaxial accelerometer</td>
</tr>
<tr>
<td>• 8 languages</td>
<td>• GPS: Provides measures of home-school-work-medical settings, as well as proximity to green space, etc.</td>
<td>• Sampled at 12.5 Hz</td>
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<tr>
<td>• Open-ended Voice Diary</td>
<td>• Screen Logs: Provide measure of Phone usage helpful in inference of sleep patterns in absence of wearable data</td>
<td>• Swapped at each visit (or via post)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Same device used in the UK Biobank (100K samples)</td>
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AX3 Axivity Wearable:
- Triaxial accelerometer
- Sampled at 12.5 Hz
- Swapped at each visit (or via post)
- Same device used in the UK Biobank (100K samples)

Digital Assessment:
- 30 questions
- 8 languages
- Open-ended Voice Diary

Digital Phenotyping:
- Accelerometer
- GPS: Provides measures of home-school-work-medical settings, as well as proximity to green space, etc.
- Screen Logs: Provide measure of Phone usage helpful in inference of sleep patterns in absence of wearable data

AX3 Axivity Wearable:
- Triaxial accelerometer
- Sampled at 12.5 Hz
- Swapped at each visit (or via post)
- Same device used in the UK Biobank (100K samples)
Digital Assessment in AMP® Schizophrenia

Enhancing Engagement Through Optionality Re: Data Collection

1. All sensors + Surveys + Voice Diary

2. Accel + Screen State + Surveys + Voice Diary

3. Surveys & Voice Diaries Only

Accelerating Medicines Partnership®

SCHIZOPHRENIA
Digital Assessment in AMP® Schizophrenia

**Digital Assessment Uptake at Consent**

<table>
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<tr>
<th>All sensors including GPS</th>
<th>Sensors <em>excluding</em> GPS</th>
<th>No Passive Data Collection</th>
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<tr>
<td><strong>All</strong></td>
<td><strong>CHR only</strong></td>
<td><strong>All</strong></td>
</tr>
<tr>
<td>363 (66%)</td>
<td>301 (67%)</td>
<td>400 (85%)</td>
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**Actigraphy Wearable**

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<td>370 (67%)</td>
<td>312 (70%)</td>
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**Surveys & Audio Diaries**

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<th>CHR only</th>
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</thead>
<tbody>
<tr>
<td>48 (9%)</td>
<td>43 (10%)</td>
</tr>
</tbody>
</table>

**No Passive Data Collection**

<table>
<thead>
<tr>
<th>All</th>
<th>CHR only</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 (85%)</td>
<td>332 (87%)</td>
</tr>
</tbody>
</table>
Digital Assessment in AMP® Schizophrenia

Examples of Detailed Individual Participant Data

Accelerating Medicines Partnership®
SCHIZOPHRENIA
Digital Assessment in AMP® Schizophrenia

Duration of Participation Re: Onboarding

# of Participants with 16+ Weeks Since Onboarding (as of 1/26/24)

- ProNET N=309
- PRESCIENT N=140
Digital Assessment in AMP® Schizophrenia

Collection of Smartphone-Based Ecological Surveys by Week of Study

Percentage of Participants Completing Ecological Surveys by Week

Data compiled from actual data received by the DPACC as of January 26, 2024.

- **Excellent**: 5 ~ 7 surveys per week
- **Good**: 3 ~ 4
- **Fair**: 1 ~ 2
- **None**: 0

For each day, count as 1 if at least some data is collected. Count as 0 if no data is collected.

- Here, amount of data collected per day is not considered.
- Zero incoming data could mean the subject have withdrawn from the study, or experiencing technical difficulties.

N=449
No relationship was detected between symptom severity and survey completion.
Data compiled from actual data received by the DPACC as of August 2, 2023.

- Excellent: data collected for 5 ~ 7 days per week
- Good: 3 ~ 4
- Fair: 1 ~ 2
- None: 0

For each day, count as 1 if at least some data is collected. Count as 0 if no data is collected.

Here, amount of data collected per day is not considered.

Zero incoming data could mean the subject have withdrawn from the study, or experiencing technical difficulties.
Digital Assessment in AMP® Schizophrenia

Collection of Smartphone-Based Passive Data by Week of Study

Data compiled from actual data received by the DPACC as of August 2, 2023.

- Excellent: data collected for 5 ~ 7 days per week
- Good: 3 ~ 4
- Fair: 1 ~ 2
- None: 0

For each day, count as 1 if at least some data is collected. Count as 0 if no data is collected.

Here, amount of data collected per day is not considered.

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Here, amount of data collected per day is not considered.

Zero incoming data could mean the subject have withdrawn from the study, or experiencing technical difficulties.
Digital Assessment in AMP® Schizophrenia

Continuous Assessment of Community / Social Functioning through Geospatial Recording

https://github.com/dptools/dplocate
https://www.medrxiv.org/content/10.1101/2022.07.05.22277276v1
Each panel shows traces of significant locations for a **single individual** with schizophrenia or bipolar disorder, followed for up to 2 yrs.

Patterns illustrate tremendous **variance between individuals** in as well as **changes over time** within individuals.

- **Location diversity**, 
- Evidence of **job/school** 
- Occurrence of other **significant life events**, e.g.,
  - moves between home locations
  - hospitalizations
  - evidence of relationships
Digital Assessment in AMP® Schizophrenia

Wearable Data Showing QA/QC Procedures and Sleep-Wake Activity in ~270 Participants

Axivity AX3 bracelet

S=# Sessions by site  N=# of Participants by site

PRESCIENT SITES

ProNET SITES

SITES

N=154

N=117

Wake
Sleep
Wake
Phone sensor data can be used to estimate sleep epochs.

Comparing to continuous wearable data, the **midpoint of sleep** is most reliably captured by phone data, with **changes** (e.g., weekday-to-weekend) consistently reflected across devices.
NDA Data Upload

- First data release successful
  - Contained data up to 1 month after onboard
  - Data released to AMP-SCZ Partners Sept 2023
  - Data released to Research Community Nov 2023

- Next data release
  - Will include Multi-Timepoint data
  - Scheduled for Spring 2024 (March > Partners; May > Community)
- Smartphone Sensor missingness is independent of survey adherence
- EMA adherence is independent of symptom severity (BPRS total)
- Both Surveys and Sensors plateau at ~50% adherence (Any data)
  - Both EMA and Sensors start around 85%
  - EMA drops to 50% around 12 weeks and keep falling gradually.
- Sensors drop to 50% >16 weeks and may plateau around 12 wks.
Digital Assessment in AMP® Schizophrenia

Mitigation strategies to reduce non-adherence of EMA, Sensor, or Wearable

- Optionality during Consent and Onboarding to encourage “Some-Better-than-None” Approach
- Robust Onboarding and Check-In procedures to systematically record and address issues when they arise
- Realtime monitoring of participant data and staff behavior to quickly address non-adherence to study measures (participants) or assessments (staff)
- Dedicated research staff for managing digital measures with participants
- Performance-based Remuneration*
- Return of Individualized Research Results to drive Engagement

* Not all measures earned payment
Thank you
Questions?

Justin Baker, MD PhD
Schizophrenia Research: 
The Contribution of Regulatory Science

Valentina Mantua, MD, PhD

Clinical Team Leader, Division of Psychiatry
Office of Neuroscience, Office of New Drugs
FDA Center for Drug Evaluation and Research
Disclosures and Disclaimer

• Nothing to disclose

• This presentation reflects the views of the speaker and should not be construed to represent FDA’s views or policies.
Outline

- Regulatory challenges in drug development for CHR
- How AMP SCZ can address these challenges
- FDA contribution to AMP SCZ
- AMP SCZ contribution to regulatory science
The Course of Schizophrenia

Stage 0
Pre-morbid

Stage 1
Clinical High Risk for Psychosis

Stage 2
Early fully recover

Stage 3
Late/incomplete recovery

Stage 4
Chronicity

Symptom Intensity

Diagnostic

Sub-threshold

Max

Min

Brain (re)organisation

Window of opportunity

Brain formation

«Risk-reduction/Self-help/Coping »

Family/Social support/Symptomatic relief

Course-alteration

«Preventive-Protective»

«Rescue-Restorative »

Years

Max

Min

Adapted from: Paolo Fusar-Poli, 2019
AMP SCZ Aims and Concept

Goal of AMP SCZ is to facilitate drug development

**Aim 1:** Provide tools to enable the selection of enriched patient populations, to considerably improve success in developing pharmacologic treatments for patients with CHR for psychosis.

**Aim 2:** Develop and validate biomarkers and outcome measures that can establish early indicators of pharmacologic treatment efficacy.
Clinical Trials in CHR

• There is no treatment approved for CHR for psychosis
  – We had very few submissions for INDs for patients at CHR

• Diagnosis of CHR is mostly based on clinical measures
  – Ultra High Risk criteria, no qualified diagnostic biomarker
  – Prediction models have moderate power in the prediction of psychosis

• No biomarker is found to be reasonably likely to predict a clinical outcome

• From a regulatory standpoint, clinical trials in CHRs could be considered secondary prevention trials
  – The use of a time-to-event survival analysis approach (i.e., time to the occurrence of a clinically meaningful event such as psychosis could be an acceptable outcome)
  – Alzheimer’s disease (Stage 1) could be a relevant regulatory example
Treatment Strategies in Neurodevelopmental Disorders

- **Primary Prevention**: Prevent the illness from developing.
- **Secondary Prevention**: Diagnose and treat the disease before it becomes advanced, and disability becomes severe.
- **Tertiary Prevention**: Reduce the impact of the disease on disability and quality of life.

**Risk Factors**

- Antipsychotics and other drugs

**Diagnosis and treatment of CHR states**

**Antipsychotics and other drugs**
Challenges when designing CTs in CHR states

- According to a meta-analysis, the risk of developing psychosis is 22% in 3 years.
- In NAPLS-2, 52% of the sample did not complete the 2-year follow up.
- About 25% of completers met criteria for psychosis.
- Large and very long studies are necessary to power for time to event analyses.
- AMP SCZ could inform the design of CTs investigating symptomatic treatments.

Adapted from: Paolo Fusar-Poli, 2019
Regulatory Considerations for Drug Development in CHR

• Definition of the population for inclusion in CTs
  – Multimodal biomarkers for enrichment (identify individuals most likely to convert to psychosis)
  – Minimize the number of individuals who receive unnecessary treatment
  – For symptomatic treatments the population may not be enriched but benefit/risk considerations are necessary

• Endpoints
  – Time to Event (psychosis)
  – Biomarker(s) reasonably likely to predict psychosis
  – Change from baseline to a clinically meaningful measure of a symptom domain (e.g., symptomatic treatment of cognition)

• Inclusion of pediatric subjects
  – Window of opportunity
  – Challenges related to the prospect of direct benefit

• Indication will be a matter of review
  – Prevention/delay in onset of first episode psychosis
  – Symptomatic treatment of intermediate outcomes (e.g. cognitive impairment associated with schizophrenia)
Clinical tools (questionnaires) to improve the definition of CHR and increase the predictive value.

Measures as biomarkers for enrichment of clinical trial populations to identify individuals most likely to convert to psychosis and thus minimizing unnecessary treatment.

Multimodal tools to improve the clinical and biological understanding of CHR states (naturalistic observation of change with time).

Multimodal tools to improve the clinical and biological understanding of CHR states (sensitivity to change in response to treatment).

Multimodal measures to be used as biomarkers to predict conversion to psychosis or remission or symptomatic states.

Measures to improve the clinical and biological understanding of individuals who do not remit and remain symptomatic.

Analysis tools including prediction models and their validation strategies to predict outcomes.

The most diverse CHR population recruited so far. This factor will increase generalizability.
# The FDA Contribution to AMP SCZ

## Steering Committee
- Regulatory input on aims and various elements of the protocol

## Operations Working Group
- Refinement of project aims
- Refinement of endpoint definition
- Harmonization of terminology to align with current regulatory thinking
- Inclusion of the PSYCHS in the Drug Development Tool (DDT) Qualification program

## Data Analytic Strategy Working Group
- Definition of the primary endpoint and secondary endpoints for analyses
- Discussion on the most appropriate validation strategy for prediction models

## Digital Biomarker and EMA Working Group
- Compliance with the FDA draft guidance for remote acquisition of data using Digital Health Technologies (DHTs)
- Discussion on appropriate DHT-derived measures to submit for qualification in different contexts of use
Conclusions

• Drug development in populations at CHR for psychotic disorders and SCZ is challenging because the clinical course of CHR states is not well characterized and there is a risk of overtreatment.

• There is a substantial lack of tools (including biomarkers) to characterize the CHR population from a clinical and biological perspective.

• At the current state of knowledge, clinical trials in CHR states could be potentially very long and require a high number of subjects.

• The AMP SCZ project is a first step for building the tools necessary to streamline drug development by designing more efficient clinical trials.

• The FDA provided and will continue providing input at various stages of the AMP SCZ project.

• AMP SCZ will substantially contribute to building a regulatory framework for the clinical investigation of medicinal products for the treatment of subjects at CHR for developing for psychotic disorders and SCZ.
Disclosures and Disclaimer

- Dr. Pandina is a full-time employee of J&J Innovative Medicine, and a J&J stockholder
- The views expressed in this presentation are those of Dr. Pandina, and do not reflect the views of J&J Innovative Medicine
Why are biomarkers (and digital measures) important for neuroscience research in psychosis?

• There have been incredible advances in our understanding of the neural basis of neuropsychiatric disorders in the past decade, including the neurobiology of psychosis

• Identified novel targets and compounds, with potential to treat symptoms, modify illness course, or prevent conversion to a psychotic disorder

• There is a critical need for research to:
  • Identify those at clinical high risk for psychosis (CHR)
  • Develop treatments to treat symptoms and prevent conversion to psychotic disorder

• Clinical trials for schizophrenia and related psychoses (still) rely on clinician symptom assessment for diagnosis and monitoring of treatment outcome

• Biomarkers, including use of digital measures, hold promise to facilitate more efficient, higher throughput clinical trials, increase signal detection, and enable precision neuroscience approaches
AMP SCZ Overview

Goal of AMP SCZ is to facilitate drug development

Aim 1: Provide tools to enable the selection of enriched patient populations, to considerably improve success in developing pharmacologic treatments for patients with CHR for psychosis

Aim 2: Develop and validate biomarkers and outcome measures that can establish early indicators of pharmacologic treatment efficacy

J&J Innovative Medicine
Traditional Neuropsychiatry Biomarkers

Why have traditional neuropsychiatry biomarkers not produced more substantive change in development of new treatments for psychosis and psychotic disorders?

For understanding neural structure and function (“pros”):
- Extensively researched, characterize the brain’s structure and function and other biological states
- Correlate with long-term clinical outcomes

For clinical trials (“cons”):
- Expensive, potentially time-consuming, require expertise and equipment
- Increase visit length, may increase placebo response?
- Used for stratification or enrichment, not Ph2 primary outcome
- Infrequently administered: impractical for rapidly changing states
- Proof-of-concept/Phase 2: typically must select a small number of measures, specifically targeting drug mechanism and anticipated effect
- Results have limited benefit in detecting drug response
- Cannot easily be used in large phase 3 confirmatory studies

Digital Biomarkers

How can digital biomarkers help change the paradigm for development of new psychosis treatments?

Digital Biomarkers in AMP SCZ Observational Study

For clinical trials ("pros"):
• Simple, minimal time/effort, mostly passive
• Frequent sampling: multiple timepoints
• Independently assessed, outside clinical trial site
• Real-time, in-the-moment (EMA) assessment of mental states, symptoms, real-world functioning

For understanding neural structure and function ("cons"):  
• Less well-established relationship to clinical states  
• Questionable relationship to brain structure and function or disease biology  
• "Voluntary" participation (for AMP SCZ participants)

• Ecological Momentary Assessments (EMA) via smart app  
  • Brief, daily questions about stress level, mood state, anomalous experiences (ie, psychotic-like experiences), and behavior.

• 2-minute daily audio recording, with analysis of content and vocal characteristics

• Geolocation

• Actigraphy (worn daily for 1st year)

• Vocal and facial affect analysis of on-site psychiatric interviews

Digital Biomarkers

Could digital measures improve signal detection in clinical trials for CHR, and revolutionize development of new medicines?

<table>
<thead>
<tr>
<th>Measure</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMA</td>
<td>• Real-time, frequent symptoms in the real world</td>
</tr>
<tr>
<td></td>
<td>• Pattern of missingness?</td>
</tr>
<tr>
<td>Audio</td>
<td>• Speech content, vocal pattern, tone, rhythm</td>
</tr>
<tr>
<td></td>
<td>• Mood state, clinical content</td>
</tr>
<tr>
<td>Geo-location</td>
<td>• Community interaction patterns, engagement</td>
</tr>
<tr>
<td></td>
<td>• “Known” locations, social rhythms</td>
</tr>
<tr>
<td>Actigraphy</td>
<td>• Validated for sleep, other activities</td>
</tr>
<tr>
<td></td>
<td>• Asses detailed activity patterns</td>
</tr>
<tr>
<td>Voice recording</td>
<td>• Compare daily audio diary with clinic voice recordings, correlate with clinical outcomes</td>
</tr>
<tr>
<td>Facial expression</td>
<td>• Assess affective expression, range, content congruence, atypicality</td>
</tr>
</tbody>
</table>
Autism Example - Eye Tracking

Machine learning approach uses eye tracking data to enhance detection of clinical trial outcome in ASD placebo-clinical trial

- Combined ET features + ADOS scores to enhance pt. inclusion
- Compared tx effect size on SRS Total Score for each model

Dotted box: Mean (SD) Cohen’s d distribution corresponding to randomly removed patients in tx and PBO groups to match the same N as selected in ML + clinical criteria approach 100 times

Stars: Cohen’s d for ADOS-2 score driven patient selection

Squares: Cohen’s d for ML ET + ADOS-2 score driven patient selection

Conclusion

Addition of ET features to clinical diagnostic scores, using model-driven ML, enhances efficacy outcome in PoC clinical trial
Mood Disorder Example - Actigraphy

Prediction of MDD relapse using actigraphy and clinical data in observational MDD trials (N=277 patients observed ≥1 year)

Actigraphy data
- Red = relapse period data for patient
- Blue = non-relapse period data for patient

Sample Entropy (SaEn) values for non-relapse and relapse sections.

<table>
<thead>
<tr>
<th>Time of day</th>
<th>Non-relapse</th>
<th>Relapse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Night (12 AM to 6 AM)</td>
<td>0.22</td>
<td>0.21</td>
</tr>
<tr>
<td>Morning (6 AM to 12 PM)</td>
<td>0.34</td>
<td>0.37</td>
</tr>
<tr>
<td>Afternoon (12 PM to 18 PM)</td>
<td>0.92</td>
<td>0.79</td>
</tr>
<tr>
<td>Evening (18 PM to 12 AM)</td>
<td>0.28</td>
<td>0.31</td>
</tr>
</tbody>
</table>

Conclusion
Balanced accuracy of ≥ 71%, false alarm rate of ≤ 2.3 alarm/ patient/ year, median relapse detection time of 2–3 weeks in advance of clinical onset in both studies
Digital measures in CHR: the road to novel therapies?

• What will compound be indicated for?
  • CHR syndrome itself impairing with functional impact, does not always convert to psychotic disorder
  • Is CHR syndrome the target, or is conversion to psychosis the target, or both?

• What is the associated CHR neurobiology?
  • Does digital measure /biomarker correlate with “known” clinical outcomes and associated neurobiology?

• Can we design a killer proof-of-concept study (“fast-fail”)?
  • Adequate Phase 2 evidence required (sample size, measures, likelihood of success, regulatory path)
  • Required the “Goldilocks” design
    • Not too big (to operate), not too long (in duration), not too slow (for a timely finish), and not too expensive
  • Analytical approach: sophisticated, but not too complex. Pre-defined algorithm(s) for biomarker/digital?

• Can the compound proceed to Phase 3?
  • Is the drug effect meaningful to patients (feels and functions)?
  • Is the digital measure or biomarker useful (for clinical outcome) and scalable?
  • Is an indication possible – is the regulatory path relatively clear?
  • Is pursuing the indication feasible?
The only source of knowledge is experience.

-Albert Einstein
Today’s Listening Experience

The Three Stages of this Presentation

1. Impact of Lived Experience
   We will explore how lived experience driven advocacy organizations helped lay the foundation and catalyze the AMP SCZ project.

2. AMP SCZ: Engagement
   Through a closer look at AMP SCZ, we will demonstrate how we’ve helped continue to move the initiative forward and provide value to stakeholders.

3. How Lived Experience Helps
   Through science and personal insights, we will discuss the evidence-based practices that can enhance lived experience engagement in research to empower your work.
1. Learning the Power of Lived Experiences
North American Prodrome Longitudinal Study (NAPLS)

- **Origin:** Starting in 2003, One Mind and NIMH convened 10 institutions across North America in a CHR risk prediction research consortium.

- **Purpose:** Develop tools to **predict the onset of psychosis** in help-seeking youth.

- **Methods:** Three linked, NIMH-funded longitudinal studies ran from 2003 to 2020, involving 2654 participants. Markers studied included clinical interviews, neurocognitive tests, EEG measures, structural MRI, stress markers, inflammatory markers, genetic indices.

- **Outcomes:** In addition to developing a prediction tool from six of the assessments, **this research formed the basis for the AMP SCZ biomarker studies.**
Advancing Discoveries Summit (ADS)

- **NAMI and Stanley Center Partnership (Since 2014):** Collaboration to lead the ADS series for large-scale mental illness research, involving stakeholders from advocacy, academia, industry, and government.

- **ADS and AMP SCZ Launch:** First meeting in 2016, leading to the 2020 launch of the AMP SCZ, a significant advocacy success.

- **Support from Shear Family Foundation:** Their donation enabled NAMI’s active participation in the AMP SCZ project.

- **Ongoing Efforts in 2023:** NAMI continued the ADS series in March 2023, building upon previous achievements and seeking new breakthroughs in mental health research.
2. AMP SCZ: Lived Experience Participants’ Engagement in Mental Health Research

Accelerating Medicines Partnership (AMP) – Schizophrenia
AMP SCZ Governance and Lived Experience Leadership

- **Co-led Governance:** AMP SCZ is steered by a committee chaired by two co-leads, one with lived experience of psychosis, ensuring empathetic and informed leadership.

- **Inclusion of Lived Experience:** Incorporating lived experience in governance enhances understanding of challenges and aspirations of those with schizophrenia, at-risk youth, and their families.

- **Direct Impact on Research:** The co-chairs contribute to the development and review of the research plan, offering expertise and ensuring participant considerations are prioritized.

- **Open-Door Policy for Lived Experience Partners:** AMP SCZ’s commitment to transparency and diverse perspectives is evident in its welcoming approach to lived experience partners, fostering genuine and effective integration.
**Research Design:** Members of the AMP SCZ consortium with lived experience reviewed the study protocols and ongoing conduct of the study.

**Patient Burden:** Members of the AMP SCZ consortium with lived experience provided insight into the biomarkers and assessments and consideration of the perceived burden from the perspective of study participants.

**Data Sharing:** Members of the AMP SCZ consortium with lived experience ensure the ethical use of sensitive digital data, and supported the establishment of a data-sharing process for participants.
Research Design, Patient Burden and Data, oh my!

“The digital assessment platform used in the AMP SCZ studies, mindLAMP, has been built over the last 5 years with direct co-design and over 200 updates so its design reflects the input of many stakeholders with lived experience. This involvement, coupled with actively sharing research data from the app back to the users, has helped to build trust and contributed to the app’s robust uptake by more than 80% of study participants. This surprisingly strong engagement is now yielding useful data to support the AMP’s aim to lay the groundwork for developing original medicines to treat people in the earliest stages of schizophrenia.”

John Torous, MD, MBI
Director of the Division of Digital Psychiatry
Beth Israel Deaconess Medical Center
Establishment of WOW (2021): Formed to oversee outreach for AMP SCZ, focusing on both researchers and CHR population.

Collaborative Leadership: Led by Brigham and Women’s Hospital, McLean Hospital, NAMI, NIMH, and FNIH, coordinating with various cores and domain teams.

Mission and Internet Presence: Developing and maintaining AMP SCZ’s online presence for widespread dissemination and targeted outreach to individuals experiencing CHR and their families.

Inclusion of Lived Experiences: Regular contributions from NAMI, OneMind, and Mental Health America ensure that efforts are informed by lived experience in mental health.

Positive Impact of Inclusive Approach: Significant referral traffic to the website from NAMI, indicating engagement with those with lived experience and their families.
Getting the Word Out!

Accelerating Medicines Partnership®
Schizophrenia: Bridging Science And Lived Experience
*NAMI Advocate*
Fall 2023

Early Indicators of Schizophrenia
*Inside Schizophrenia Podcast*
August 16, 2023

Early Intervention for Schizophrenia on the Horizon: Implications for Clinicians and Patients
*Psychiatric Times*
April 18, 2023

He Who Has Hope, Has Everything
*Psychiatric Services*
Feb. 15, 2023

Accelerating Medicines Partnership – Schizophrenia
with Dr. Joshua A. Gordon and Carlos Larrauri
*One Mind Brain Waves*
May 27, 2022

Leading Science With Lived Experience
*Schizophrenia Bulletin*
May 2, 2022

and **more!**

Content on following slides is from *Transforming How We Work: Reflections from HBGI’s Lived Experience Council on Embedding Lived Experience Into Organizations and Services*. 

Credit: zonadearte / DigitalVision Vectors / Getty
Why Embed Lived Experience?

Integrating lived experience into research design fosters:

- Improved research quality and accessibility
- More tangible outcomes for the intended population
- Hope and empowerment for service users and advisors
- Decreased stigma and enhanced trust
**BEST PRACTICES**

### Success Factors to Embed Lived Experience

As recommended by HBGI’s Lived Experience Council

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>1. Culture</strong></td>
<td>Provide a welcoming environment to encourage robust exchange and win/win success among diverse stakeholders.</td>
</tr>
<tr>
<td><strong>2. Systems</strong></td>
<td>Ensure that lived experience participation is reliably and sustainably integrated organizationally.</td>
</tr>
<tr>
<td><strong>3. Resources</strong></td>
<td>Ensure that your team has the resources to support lived experience participation fairly and equitably.</td>
</tr>
</tbody>
</table>
Success Factor: Culture

- **Embrace diversity**
  - Capture the breadth of patient community
  - Use many dimensions

- **Foster inclusivity & wellbeing**
  - Provide welcoming environments
  - Actively encourage self-expression

- **Support adaptability**
  - Co-design roles with participants
  - Work toward best fit

- **See strengths beyond lived experience**
  - Harness professional skills
  - Embrace the whole person
Choose governance structures that are fit for purpose

- Systematize live experience participation
- Co-design systems with lived experience participants

Create avenues for open communication

- Facilitate dissemination of lived experience perspective
- Ensure leadership accountability to lived experience members
**Success Factor: Resources**

**Support skills development**
- Through judicious selection
- Through training

**Provide Logistical Support**
- Pay participants competitively
- Ensure all have access to collaboration tools

**Assess Organization’s Resources**
- Ensure orgs can sustain lived experience involvement
- Consider hiring a coordinator
Moving Forward

Anticipation & Excitement: Eagerly awaiting the start of the proof of principle study—a groundbreaking step forward.

Gratitude to the Scientific Community: Immense gratitude to the dedicated scientists and researchers—your efforts bring hope to those affected.

Impact on Clinical High-Risk Individuals: The focus on identifying CHR individuals and developing predictive tools and treatments is novel and needed.

Vision for the Future: Optimistic about the study's potential to transform the approach to mental health care, particularly in early diagnosis and treatment.
Thank You! Questions?