Collecting and Sharing Patient Data:
Guiding Principles, Governance, and Sustainability

A FasterCures TRAIN Webinar

April 7, 2021

TRAIN: The Research Acceleration & Innovation Network

TRAIN's objectives are:
- To encourage more entrepreneurial philanthropy in medical research
- To build more and better networks with other R&D stakeholders
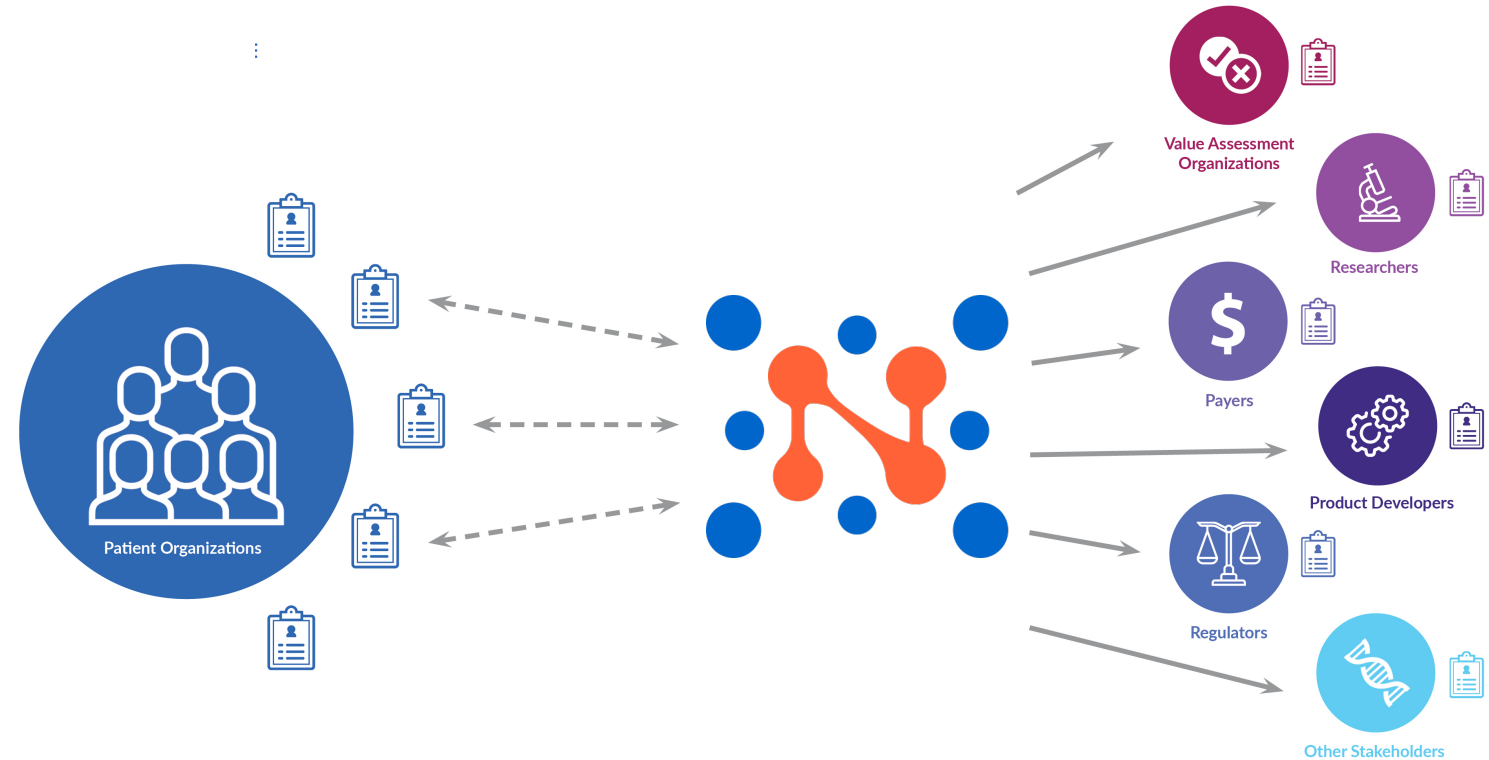- To enhance the influence of the network

FasterCures Updates for TRAIN

- Resources

  - TRAIN [Website](#)

  - Release of the Research Partnership Maturity Model and Toolkit (coming soon)

  - TRAIN Newsletter (coming soon)

- Opportunities

  - Mentorship and leadership development through [FasterCures LeadersLink](#) and Rare as One Mentorship Program

    - Currently seeking TRAIN leaders to serve as new potential mentors for Rare as One organizations (**Deadline to volunteer**: **April 19**)

- Events

  - Additional webinars and workshops to build TRAIN organizational capacity

  - Milken Institute Events

    - Future of Health Summit: June 22-23, 2021 (Virtual)
    - Partnering for Patients Forum: December 7, 2021 (Virtual)

Patient Insights Navigator

What is PIN?

- An online, searchable catalog of abstract-like summaries describing patient developed, co-developed, or approved patient insight data resources

- A tool which can inform research, product development, advocacy, patient engagement activities, or other healthcare decisions

- A primary reference of existing patient insight resources

- An opportunity to facilitate broader and deeper connections between the healthcare ecosystem and patient organizations

Patient Organizations

Value Assessment Organizations

Researchers

Payers

Product Developers

Regulators

Other Stakeholders

MILKEN INSTITUTE

Patient Insights Navigator

Why PIN?

- There is wide recognition for the need to understand patient perspectives and experiences in order to deliver better, more targeted treatments and healthcare services

- An increase in patient engagement efforts has correlated with an increased burden to patient organizations to respond to stakeholder requests

- There is an opportunity to streamline and improve on the communication between stakeholders and patient organizations

Next Steps

- Continue to identify early users
- Continue to assemble real information posts for upload to the Navigator
- Publicized launch expected Fall 2021

Panelists

MODERATOR

Caren Heller

Chief Scientific Officer, Crohn's & Colitis Foundation

David Walton

Chief Executive Officer, T1D Exchange

Sharon Terry

Chief Executive Officer, Genetic Alliance

Kristin Schneeman

Director, FasterCures

MILKEN INSTITUTE

Caren Heller

Chief Scientific Officer

Crohn's & Colitis Foundation

Outline

|	
Tied to Mission	■ Advancing our mission through IBD Plexus
Unique	■ IBD Plexus differentiators
Data	■ Data collected ■ Consent, security, privacy, use
Sustainability	■ Integral to the community ■ Governance and Plexus users
Conclusions	■ Key takeaways

Advancing our mission to find cures and improve quality of life through IBD Plexus capabilities

Discovery/Validation

- Drug targets
- Biomarkers
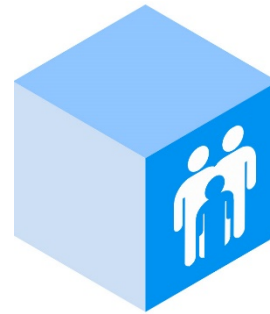
Clinical Development

- Clinical trial support
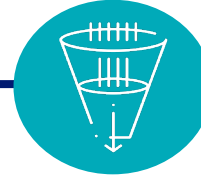
Access and Impact

- Measuring real world experience and outcomes

IBD Plexus Differentiators

Role of Foundation

- Convener of the IBD Community
- Holder of patient trust
- Deep understanding of IBD

Robust Data

- Individual-level, multi-dimensional data
- Centralized infrastructure
- Central labs
- Access to real-world data
- Recontacting patients for data/studies

Excellence & Accountability

- Proven track record
- >24,000 patients in research cohorts
- Recognized as a modern registry by FDA
- Patient consent for data to be used for research
- Compliant with HIPAA technical requirements

Data Collected

Connects fragmented health data to advance patient-centric research and understand disease holistically
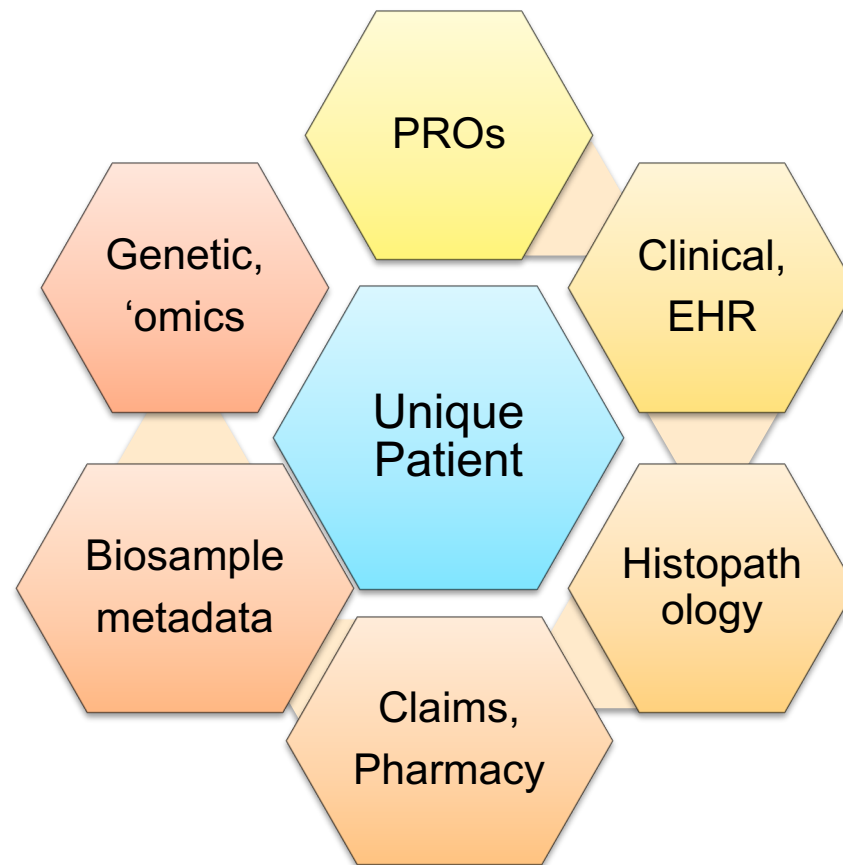
All About The Data

PATIENT CONSENT

- Process to ensure easy to read
- Provide informed consent and authorization for HIPAA and health plan data
- Broad future use of data/samples
- For academic/industry research
- Link to outside data sources
- Recontact patients for more information and studies

SECURITY AND PRIVACY

- Meets all technical safeguards required by HIPAA/HITECH Act
- Identifying data stored in separate database
- Researchers access only anonymized data
- Biobanks/central labs use coded IDs, not personal identifiers

IBD PLEXUS®
CROHN'S & COLITIS
FOUNDATION

More About The Data

DATA-USE TERMS

- Established data use agreements need to be signed

- Researcher/company agrees to safeguard storage of the data and prevent attempts to re-identify individuals

- Data cannot be used for product promotion, marketing, targeting segments of the physician IBD landscape to understand prescribing patterns

- Accommodate data sharing requirements for journals/funders

BIOSAMPLE-USE TERMS

- Established material transfer agreements need to be signed

- Requests for use and numbers are defined within specific project proposals, which must be approved by the IBD Plexus Project Selection Committee

- Raw data derived from biosamples return to IBD Plexus after specified exclusivity periods for all researchers to use
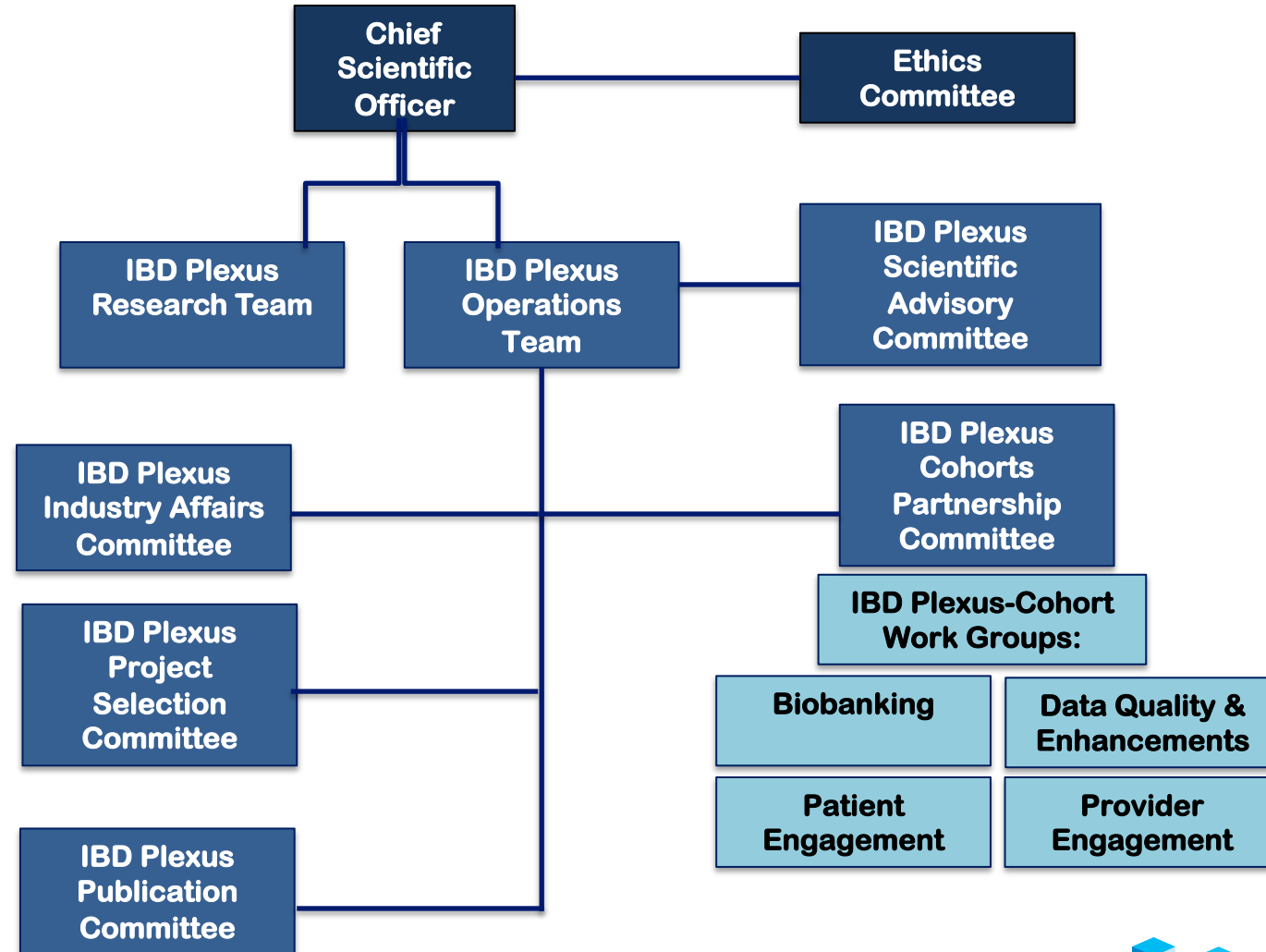
IBD PLEXUS®

CROHN'S & COLITIS FOUNDATION

Sustainability: Integral to the IBD Community

plexus [noun]:
any structure containing a complex intricate network of parts

Optimize for the present and prepare for the future to attract and retain academic and industry users:

- **Look for vendors / partners with long-term mindset and commitment to mission**
- **Recognize and meet current user needs**
- **Hear from many voices about future user needs**
- **Implement changes/capabilities to meet these needs**

IBD Plexus Governance

IBD Plexus Users

INDUSTRY

- Full membership:
  - Multiple projects
  - Engaged in planning/input
  - Precompetitive research opportunities
  - Multi-year membership fee
- Limited membership
  - Single project focus
  - Short-term membership fee

ACADEMIC

- Research cohorts
  - Individual and collaborative projects
  - Considered members of Plexus
- Academic membership
  - Individual investigators
  - Short-term membership fee

ALL USERS

- Access to biosamples with approval of Project Selection Committee
- Prep-to-research tools
- White glove service

Attracting researchers from the **entire** IBD field

> 50 Proposals

> 80 Investigators

> 30 Academic Institutions

10 Life Science Companies

5 Grant Awards (NIH, CDC, PCORI)

Conclusions

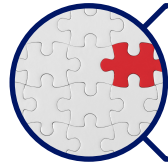**It's a huge undertaking!**
And not for the faint of heart!

It can be transformative and create lots of opportunities

All stakeholders need to be engaged on the journey in meaningful ways

The value proposition needs to match between the nonprofit and the user

It needs to become indispensable to the disease ecosystem to be sustainable

Dave Walton

Chief Executive Officer

T1D Exchange

T1D Exchange Patient Data

"TRAIN Webinar

April 7, 2021

We are focused on building the most robust and relevant set of real-world evidence (RWE) across the T1D community

- Nonprofit research organization w/ HQ in Boston

- Harnessing data to advance type 1 diabetes care

- Integrating patient experience (PWD) to drive more impactful research

- Becoming the premier data partner for the entire T1D community

T1D Exchange

T1D Exchange: Key Initiatives with varying associated data

- Quality Improvement Collaborative
  - 35 centers (48,000+ patients) w/ goal of 40 (>50,000 T1D patients) by year-end
  - Data provided by centers to T1D Exchange via Data Use Agreements
- Online Patient Registry
  - 12,500+ participants
  - 8,000+ have completed questionnaire (majority use diabetes devices)
  - Patients are screened, consented and join a longitudinal study under IRB (WIRB)
- Online Community (formerly called "Glu")
  - 28,000+ total subscribers (13,000+ active users)
  - Individuals sign up via email (3/4 are T1D and 1/4 caregivers/other)
  - Approximately 400 responses for each Question of the Day
- Custom Research
  - Sponsored projects include surveys, focus groups, interviews and custom data analysis
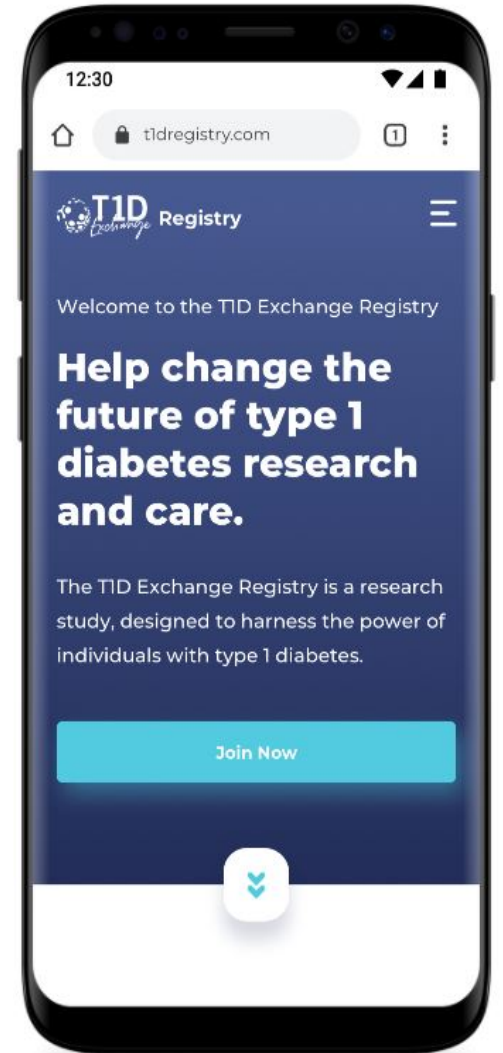
Registry

t1dregistry.org

Registry Overview

Longitudinal study that seeks to create a well-characterized cohort of people living with type 1 diabetes in the US

Participants can sign up for other studies on various topics related to T1D

Goals:

- Create a well-characterized cohort of T1D patients, including underrepresented populations in research
- Improve awareness of and facilitate enrollment into T1D research studies and clinical trials
- Gather longitudinal data on disease, health status, and self-reported outcomes
- Generate evidence to support policy/insurance coverage changes that help the T1D community

Primary Data Collected in Registry (Patient-Reported)

Baseline Questionnaire*

- Demographic
- Socioeconomic
- Clinical
  - Age and date diagnosis
  - A1C
  - Care team
  - Family history T1D, T2D
  - Other comorbidities
- Diabetes management
  - Insulin brand
  - Insulin delivery method & brand
  - BGM/CGM use and brand

Annual Questionnaire*

- Longitudinal data collection
  - Selected demographic
  - Selected socioeconomic
  - General health information
  - A1Cs
  - Diabetes management
- Self-reported outcomes
  - DKA
  - Hyperglycemic events
  - Hypoglycemic events
- Glucagon prescribing

*COVID-19 questions added May 2020

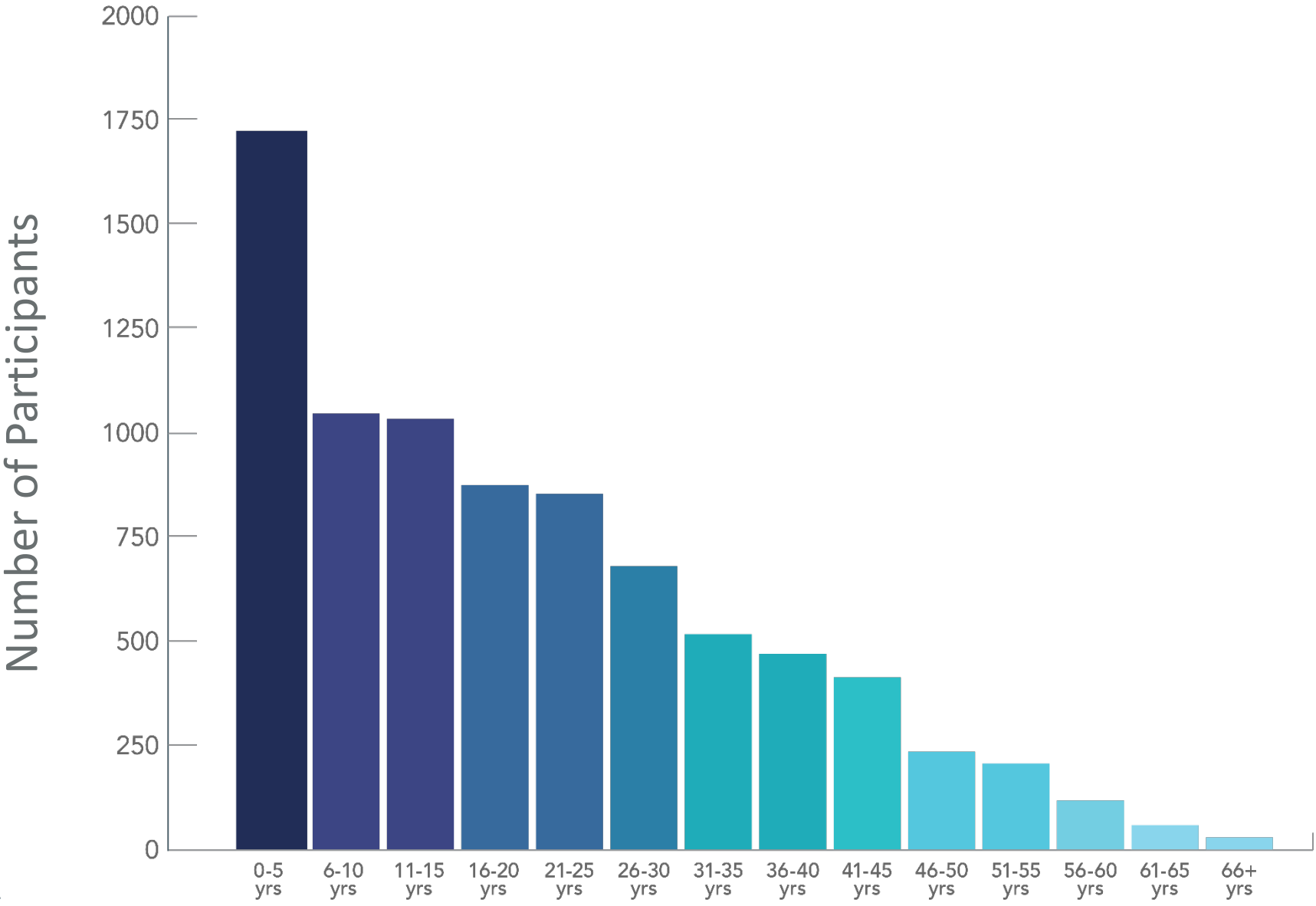# Registry is well-represented across the age spectrum
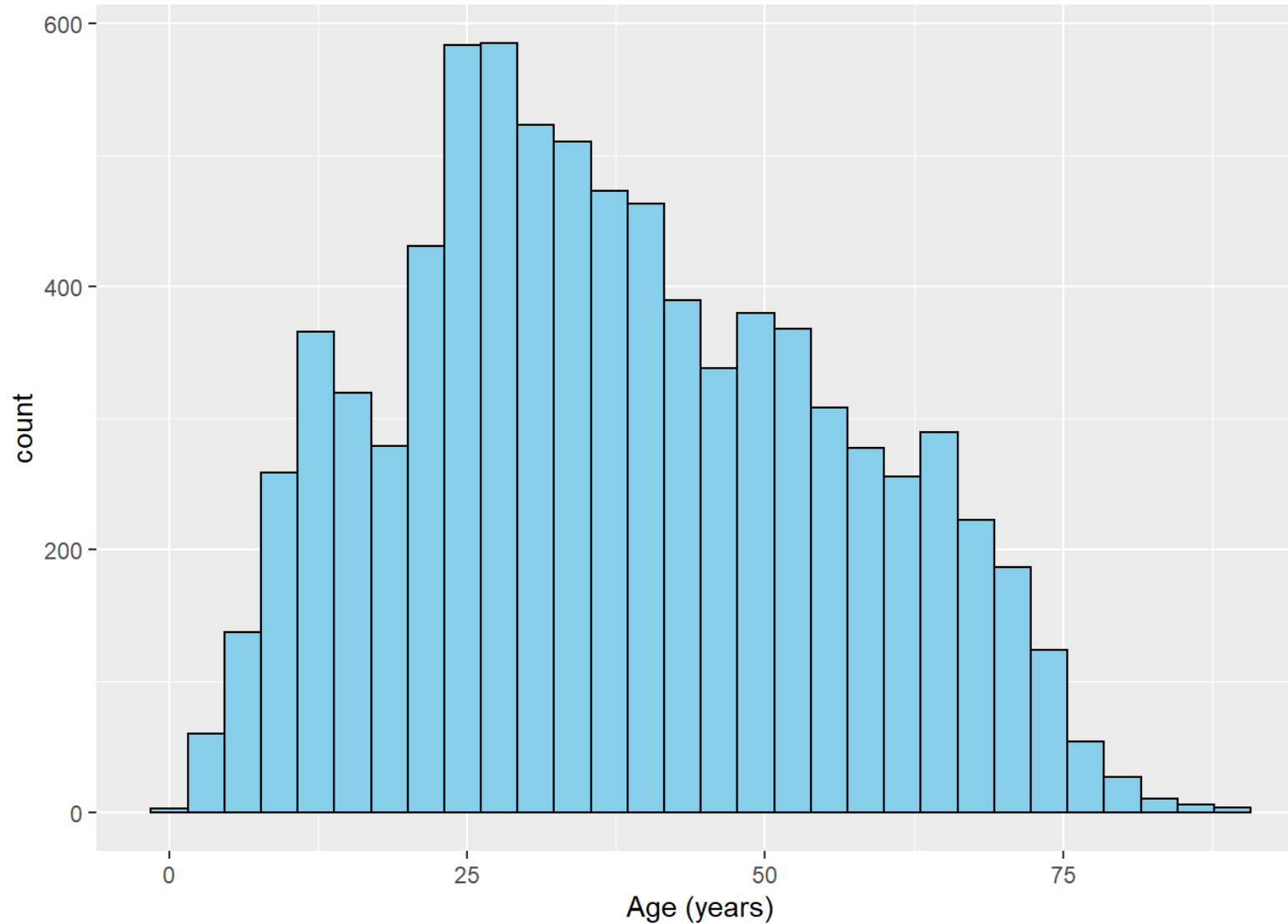
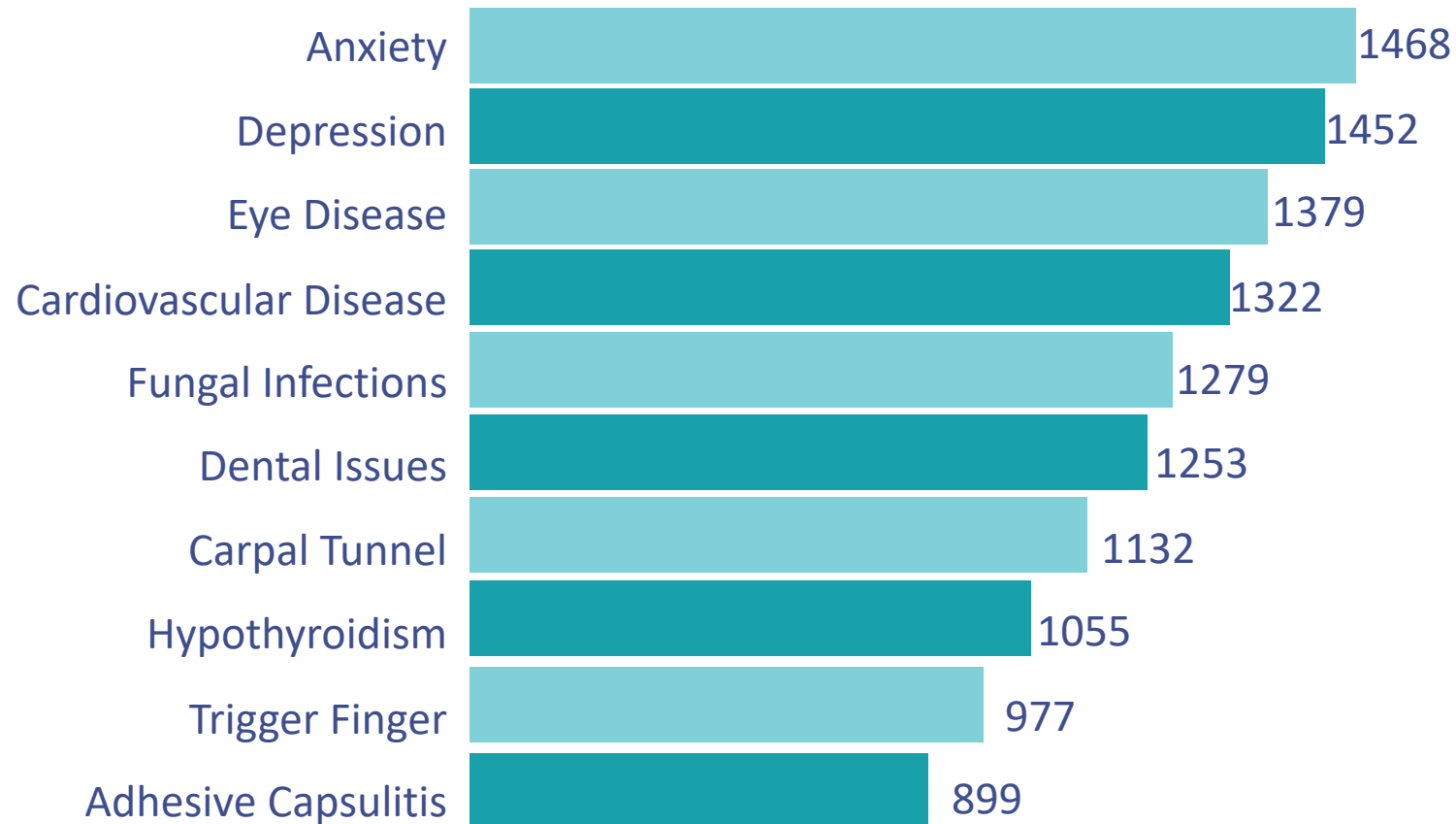# Registry Cohort Spans all 50 States and Puerto Rico
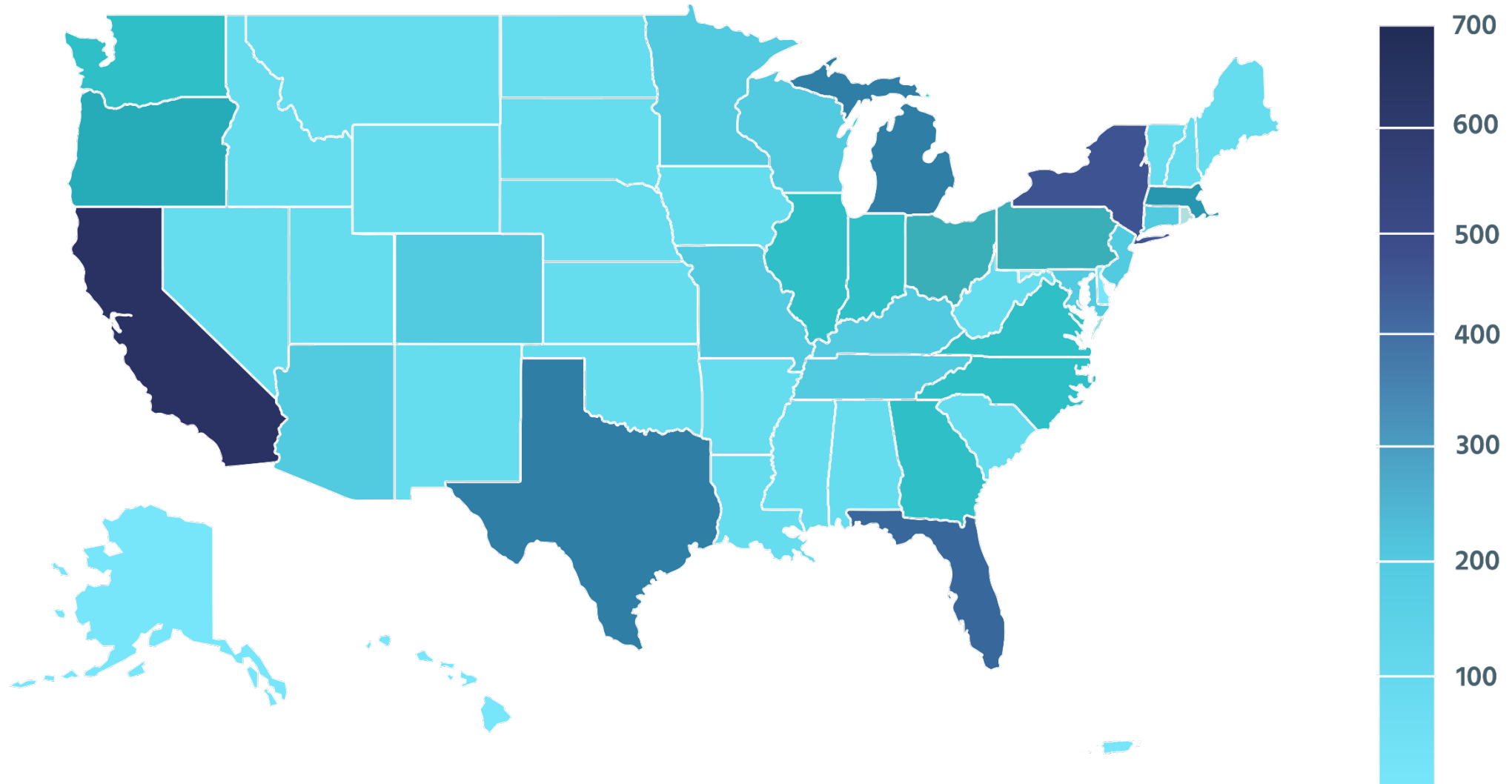
As of 3/22/2021

Years since Diagnosis

Examples of Self Reported Conditions (Total N= 8,230 individuals)

Condition	Count
Anxiety	1468
Depression	1452
Eye Disease	1379
Cardiovascular Disease	1322
Fungal Infections	1279
Dental Issues	1253
Carpal Tunnel	1132
Hypothyroidism	1055
Trigger Finger	977
Adhesive Capsulitis	899

As of 3/22/2021

T1D Exchange

Registry patients are heavy CGM & insulin pump users

6,418
Total CGM Users

Insulin Delivery Method

5624
Insulin Pump
(tubed pump, closed-loop, pod included)

2251
Insulin Pen

1030
Syringes

85
Inhalable

CGM by Manufacturer

dexcom   **4,552**

Medtronic   **1,274**

Abbott Diabetes Care   **448**

Insulin Pump by Manufacturer

Medtronic   **2,246**

TANDEM DIABETES CARE   **1,623**

Insulet Corporation   **1,374**

As of 3/22/2021

T1D Exchange

We will continue exploring other data integrations 2021-2022

- General Health/Lab Data

- CGM/Pump Data (in-process)

- Health / Claims Data

- Other Device Companies

Privacy and Data Management

- Participation is completely voluntary
- All participant information is kept confidential
- Use identifiers in place of name / stored in encrypted database
- Role-based access to data
- Some staff have Tableau to view rolled up statistics (no identifiable data)
- Can opt out / stop participation in registry at any time by contacting Registry staff at T1D Exchange

Sponsored Research or Study Promotion

- We conduct sponsored research projects using our Registry data
- We can easily target individuals for participation who have opted in to being contacted for available research
- Conduct in-depth interviews, focus groups, and surveys
- Can also conduct custom analysis of device data shared by patients
- Also promote studies to our Registry participants and online community
- These projects anticipated to fund >30% of 2021 operating budget

T1D Exchange Partners and Industry Members

Partners

THE LEONA M. AND HARRY B.
HELMSLEY
CHARITABLE TRUST

American Diabetes Association.

Beyond Type 1

CDN
COLLEGE
DIABETES
NETWORK

JCHR
JAEB CENTER FOR HEALTH RESEARCH

JDRF
IMPROVING LIVES.
CURING TYPE 1 DIABETES.

TIDEPOOL

Children with Diabetes®
www.childrenwithdiabetes.com

Industry Members / Clients

Abbott
Diabetes Care

ABVANCE
THERAPEUTICS

admetsys
ADVANCED METABOLIC SYSTEMS

bigfoot
BIOMEDICAL

Dexcom
CONTINUOUS GLUCOSE MONITORING

dreamed
DIABETES

DIATECH
DIABETES

glooko

Insulet Corporation

JUPITER
LIFE SCIENCE CONSULTING

Lexicon
pharmaceuticals

Lilly

Lifescan

MannKind Corporation

Medtronic

SANOFI DIABETES

TANDEM
DIABETES CARE

VERTEX

xeris
PHARMACEUTICALS

ZEAL&
ZEALAND PHARMA

T1D
Exchange

Appendix

Patient Registry: CGM Data Integration
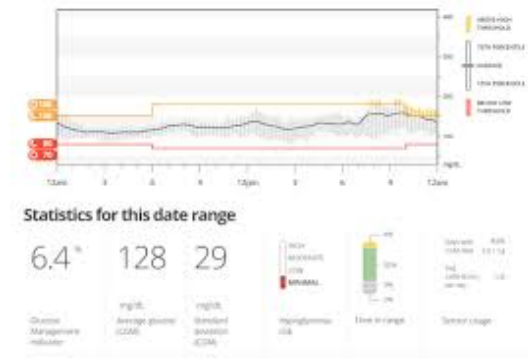
Objective
- Integrate relevant CGM data for patients in registry to expand research capabilities

Description
- Use Dexcom API to incorporate the "Clarity" account information into the registry data environment

Status
- We have 4,500 Dexcom users currently in the Registry
- Linked Clarity accounts w/ custom survey for about 1,000 participants

Next Steps
- Roll out plan to rest of Registry participants using Dexcom
- Explore CGM integrations with other players

Health Insurance

Type	Count	%
Private Health Insurance	5,624	69.7
Medicare	938	11.6
Medicaid	842	10.4
Affordable Care Act (ACA) Plan	300	3.7
Military health care	206	2.6

N = 8,064; includes persons who report more than one option

Race and Ethnicity

Race	Count	%
White	7,680	93.4
Black or African-American	291	3.5
Other	268	3.3
Asian	127	1.5
American Indian/Alaskan Native	126	1.5
Native Hawaiian or Other Pacific Islander	27	0.3

N = 8,224; includes persons who report more than one race

Ethnicity	Count	%
Not Hispanic or Latino	7,710	93.8
Hispanic or Latino	508	6.2

N = 8,218

T1D Exchange Online Community

T1D Exchange online community is a platform for individuals living with type 1 diabetes and members of their support network

- Our online community contains over 28,000 subscribers

- 12,000+ active users regularly engage in some of the following benefits

  - Answer "Question of the Day"

  - Explore relevant content and connect with others

  - Participate in academia and industry sponsored surveys and studies

Example: T1D Exchange Question of the Day: December 14, 2020

How many appointments did you have in 2020 with your main diabetes healthcare provider?

- 347 people responded

- 30% of people said they had 4 appointments

- 3% of people said they had no appointments

- 25 comments
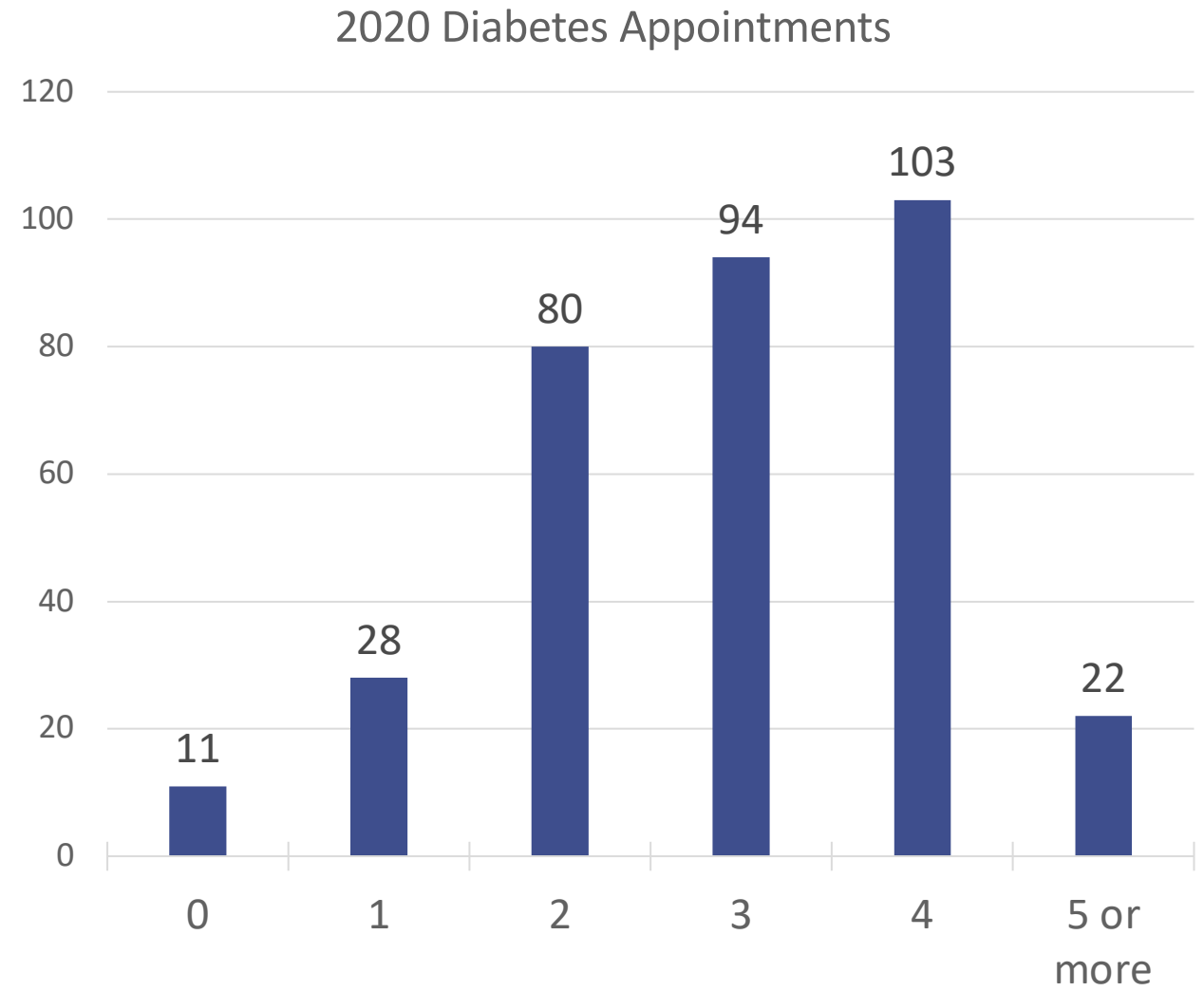
2020 Diabetes Appointments

Sharon Terry

Chief Executive Officer

Genetic Alliance

The Promise for Engaging Everyone Responsibly Team

Dawn Barry
LunaPBC, Inc.
President + Co-Founder

Sharon Terry
Genetic Alliance
Chief Executive Officer

Scott Kahn
LunaPBC, Inc.
Chief Privacy & Information Officer

Katherine Lambertson
Genetic Alliance
Director, People-centered Research

Kirby Bloom
LunaPBC, Inc.
Chief Technology Officer

Debora Thompson
LunaPBC, Inc.
VP, Strategy & Operations

Ian Terry
LunaPBC, Inc.
Senior UX Researcher

Matthew Caffet
Genetic Alliance
Program Coordinator

Genetic Alliance

luna PBC™
A Public Benefit Corporation
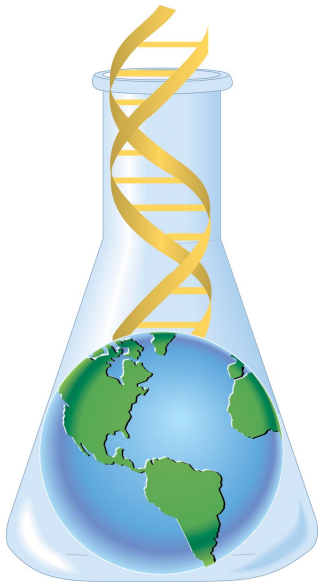
PXE international

BioBank

Gene Discovery
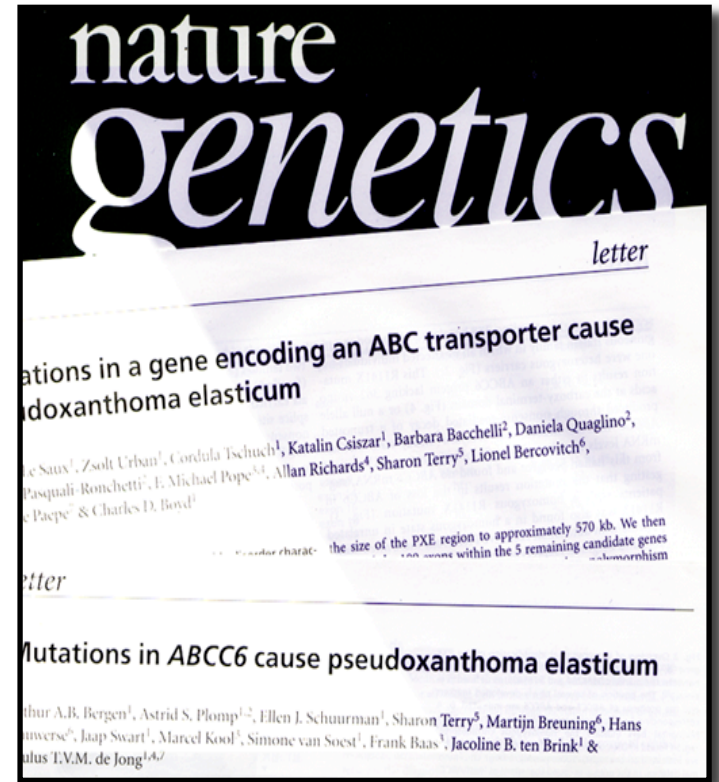
nature genetics
letter

...ations in a gene encoding an ABC transporter cause ...doxanthoma elasticum

...e Saux[1], Zsolt Urban[1], Cordula Tschuch[1], Katalin Csiszar[1], Barbara Bacchelli[2], Daniela Quaglino[2], ...Pasquali-Ronchetti[2], F. Michael Pope[3,5], Allan Richards[4], Sharon Terry[5], Lionel Bercovitch[6], ...e Paepe[7] & Charles D. Boyd[1]

...order charac- the size of the PXE region to approximately 570 kb. We then ...100 exons within the 5 remaining candidate genes

letter

Mutations in *ABCC6* cause pseud*oxanthoma elasticum*

...thur A.B. Bergen[1], Astrid S. Plomp[1,2], Ellen J. Schuurman[1], Sharon Terry[5], Martijn Breuning[6], Hans ...uwerse[5], Jaap Swart[5], Marcel Kool[5], Simone van Soest[1], Frank Baas[3], Jacoline B. ten Brink[1] & ...ulus T.V.M. de Jong[1,4,7]

Testing

Clinical Diagnostic Test Development via FDA & CLIA Regulatory Strategies

June 2001

IP WORLDWIDE

Nanotechnology: A New Patent Frontier

Seeing The Light

How The Terry Family's Fight Against Blindness May Change The Course Of Medical Research And IP Law
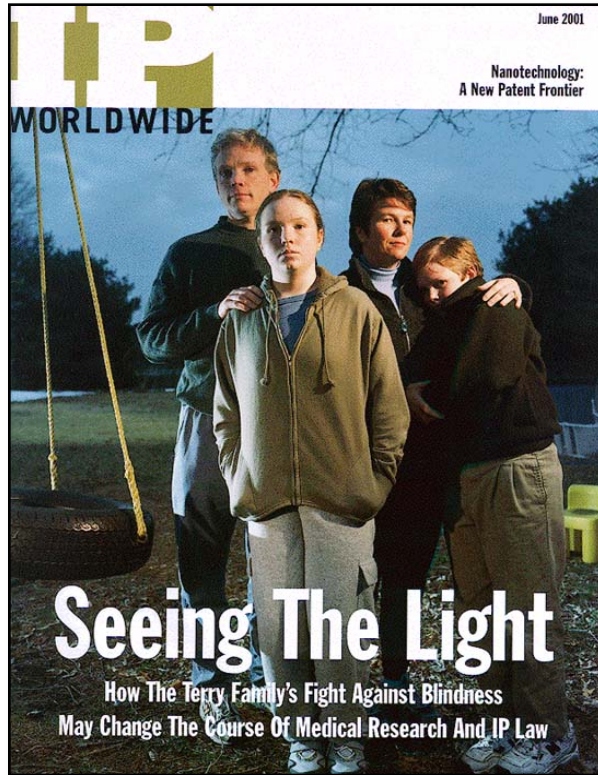
Patenting

Licensing & Intellectual Property Management

Human Clinical Trials

Drug Screening & Development Approaches

Therapeutics
--Small Molecules
--Nonsense mutants

Genetic Alliance

Promise for Engaging Everyone Responsibly

PEER

Genetic Alliance BioBank

WikiADVOCACY

Expecting Health
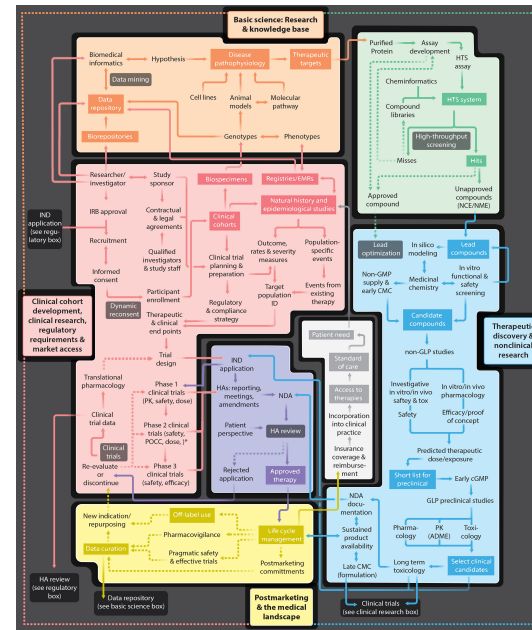
Navigating the Ecosystem of Translational Science NETS

DISEASE INFOSEARCH
Powered by Genetic Alliance

Advocacy ATLAS
...Accessible Tools for Leadership and Advocacy Success
About the ATLAS

DATA SHARING

Power to the People: Participant

Own

Sharon F.

Participati
mation of
participan
time has c

Jane Kaye, Liam Curren,
Nadja Kanellopoulou, Da
James Shepherd, Patrick

SCIENCE AND SOCIETY

From patie
participant
in biomedic

SCIENCE TRANSLATIONAL MEDICINE | EDITORIAL

POLICY

The study is open: Participants are now recruiting investigators

Recent events inspire optimism that a new age is dawning, one in which lay people have an active role in advancing biomedical research and health care delivery. Two ongoing experiments will deeply involve the public in these endeavors: the U.S. Precision Medicine Initiative (PMI) and the National Patient-Centered Clinical Research Network (PCORnet). PCORnet has already launched 20 patient-powered research networks designed to be led and animated by people who have an affinity with one another because of either shared disease, geography, experience, or identity (1). When U.S. President Barack Obama announced the PMI, he stated emphatically that the investigators and not by all stakeholders. Participants want not only to be invited to the table but also to design and host the meal with other stakeholders. There is a great deal of "us and them" language in biomedical research. Investigators point to "those patients," and activists complain about "those investigators." Clinicians are often left out of the process completely. When these roles are considered dichotomous and separate instead of part of a continuum, it is difficult to create authentic partnerships.

Participants have a place throughout the research continuum, including the proposal and prioritization of research questions, study design, engagement of study participants and their recruitment and retention, conduct

Sharon F. Terry, President and CEO of Genetic Alliance, Washington, DC 20008, USA, and serves as a member of the PCORnet leadership and the Cohort Advisory Panel of the U.S. Precision Medicine Initiative. Email: sterry@geneticalliance.org

Why does Genetic Alliance run a registry system? (Philosophy)

Building on demand to replicate the 1995 PXE International Registry

Established Genetic Alliance Registry and Biobank in 2003 – no one else doing it, or wanted to do it

Believe communities are drivers to registries and studies, and are the best long term relevant stewards

Believe communities are the best representatives of their member's needs

Believe people should control access to their data

People should receive results – of tests and studies

The biomedical industrial complex should be in service to those who need it

Why does Genetic Alliance run a registry system? (Methods/process)

We have too much in common, registries must be cross-condition

Data standards and quality are paramount

Privacy and security requirements must be met and exceeded in the
    service of the goals

Collaborative learning is enabled

Consortium based governance is critical

New business models are emerging and are supported

The mechanism should be as easy as other collective solutions

Evolution from 2003 - present

2003 – Established the BioBank, Registry, and IRB, used Filemaker Pro (don't laugh)

2008 - REDCap undergirded the system

2014 – Partnership with Private Access: Bespoke solution to allow each person to control data

2019 – Partnership with LunaPBC – the public benefit corp that runs LunaDNA (the technology platform)

LunaDNA promotes people from **subjects of research** to **partners in discovery** to transform research.

Operationalized with Privacy by Design

- Global trend has been to consider the control of an individual's privacy as a basic human right of the individual that they control

  - HIPAA in the USA
  - PIPEDA in Canada
  - APPI in Japan
  - GDPR enacted May 2018 for members of the EU
  - Data Protection Act 2018 in the UK
  - CCPA in California
  - LGPD in Brazil
  - POPI Act in South Africa

- Identifiable data, "personal" data, distinguishable data

How We Fit Together

	Create Communities	Understand Research Needs	Design Study	Recruit, Collect Data & Monitor Study	Analysis	"Publish"	Post-Market Surveillance
Genetic Alliance Services	Registry Bootcamp Genetic Alliance BioBank PEER Promise for Engaging Everyone Responsibly	Engagement Expertise PEER Promise for Engaging Everyone Responsibly	Genetic Alliance IRB *(est. procedures and subsidized pricing)*	At-home & Telemedicine Clinical Study Services BioBank			Engagement Expertise PEER Promise for Engaging Everyone Responsibly
LunaDNA Services	Intelligent Referrers Member Experience	Methodology Expertise Survey Builder™ + Card Sort	Study Designer™ IRB-Gated Workbench	Data Collection Tools Recontact Agent™ Study Designer™ Genetic Testing Vendor support	Insight Workbench™ *(Including Tableau, Jupyter Notebooks and R, Python, Hail integrations)*	Journal & Regulatory Submission Support Integrated Healthcare Services *(e.g., GC telehealth)*	Survey Builder™ Study Designer™ Recontact Agent™

Community Creation and/or Support

Genetic Alliance Qualifications Today

Genetic Alliance's 35 years of community engagement

"How are we trustworthy?" Not: "You should trust us."

- From N-of-1 to common conditions, and everything in between

- Community Based Participatory Research

- PCORnet Engagement Tools Author

- Grassroots Community Organizing – trained by Obama's campaign team

- High Tech (digital, social) & High Touch (community members)

- Nudge and nurture campaigns

- Engagement throughout the process

HELP FIND A CURE FOR KCNT1 EPILEPSY

Every parent in our KCNT1 community is hoping to find a treatment to give our children a better life. As we get closer to that reality we need to gather information from you about the many challenges of raising children with KCNT1 epilepsy.

In Phase 1 we are asking all parents or caregivers to tell us about your experience caring for your child so we can understand what is most important to you.

In Phase 2 we are asking you to enroll your child where we will begin to better understand the effects and progression of KCNT1 epilepsy.

SETH GREENBLOT, KCNT1 EPILEPSY FOUNDATION FOUNDER

REGISTER FOR THE RESEARCH COMMUNITY

Ensure Worldwide, not Just US Compliance as Data Privacy Legislation Continuously Evolves

Privacy

RECONTACT PREFERENCES

By joining a community or study, you agree to receive messages fr

You may choose if other communities are able to contact you bel
your name or other personal information

○ Yes
● No

MEMBER ACCESS

You can enable o
belong to.

mitoSHARE Regs

Contact Ir
Allow mito

Individual
Allow mito

Email Preferences
We'll always ema

Spotlight
Learn about

Newsletter
Receive monthly announcements and updates from LunaDNA.

Programs
Hear about exclusive access to offers, partners, and upcoming eve

Consent

View our Consent Form ↗ and Privacy Pol
Download/print your Signed Consent Form

REVOKE CONSENT

Please note: If you revoke this consent, we
research. You will also forfeit any shares in

REVOKE CONSENT

Delete Account

Warning: This will delete your entire acco
you have linked to your account.

To keep your Minor and Ward accounts a
your data and prevent its use in research
manage.

DELETE ACCOUNT

My Data

View and manage your contributed data. This currently includes any DNA files, Surveys, and Electronic Health Records you've submitted.

File type	Status	Download	Delete
Do You Get Enough Sleep? Added 9/25/20	SUCCESS	↓	DELETE
Sleep Apnea Added 9/25/20	SUCCESS	↓	DELETE
Alcohol Consumption Added 9/10/20	SUCCESS	↓	DELETE
COVID-19 Health Status & Behaviors Added 6/18/20	SUCCESS	↓	DELETE
Nutrition Added 6/3/20	SUCCESS	↓	DELETE
Vital Signs Added 11/9/20	SUCCESS	↓	
Vital Signs Added 11/9/20	SUCCESS	↓	
Results Added 11/9/20	SUCCESS	↓	
Results Added 11/9/20	SUCCESS	↓	
FamilyTree DNA DNA File Added 6/11/19	SUCCESS	↓	DELETE

Rows per page: 10 ▾   711-720 of 724 |< < > >|

ⓘ To remove Electronic Health Records from LunaDNA, you need to remove the Patient Portal that they came from. You can do this using the My Connected Portals table below.

⬇ DOWNLOAD ALL OF MY ELECTRONIC HEALTH RECORDS

My Connected Portals

ADD & MANAGE CONNECTIONS

Manage your patient portals here. You can add, edit, refresh and remove different portals for which you have an online account.

Once a patient portal is successfully connected, your Electronic Health Records will be displayed above.

Portal Name	Status		
Scripps Health Last synced 1/19/21	SUCCESS	DISCONNECT	DELETE

Participants can

- Control who can contact them and for what reasons

- Grant special access to registry sponsors, community leaders

- Delete their account at any time

- Revoke consent at any time

- Delete their data at any time

Understanding Research Needs
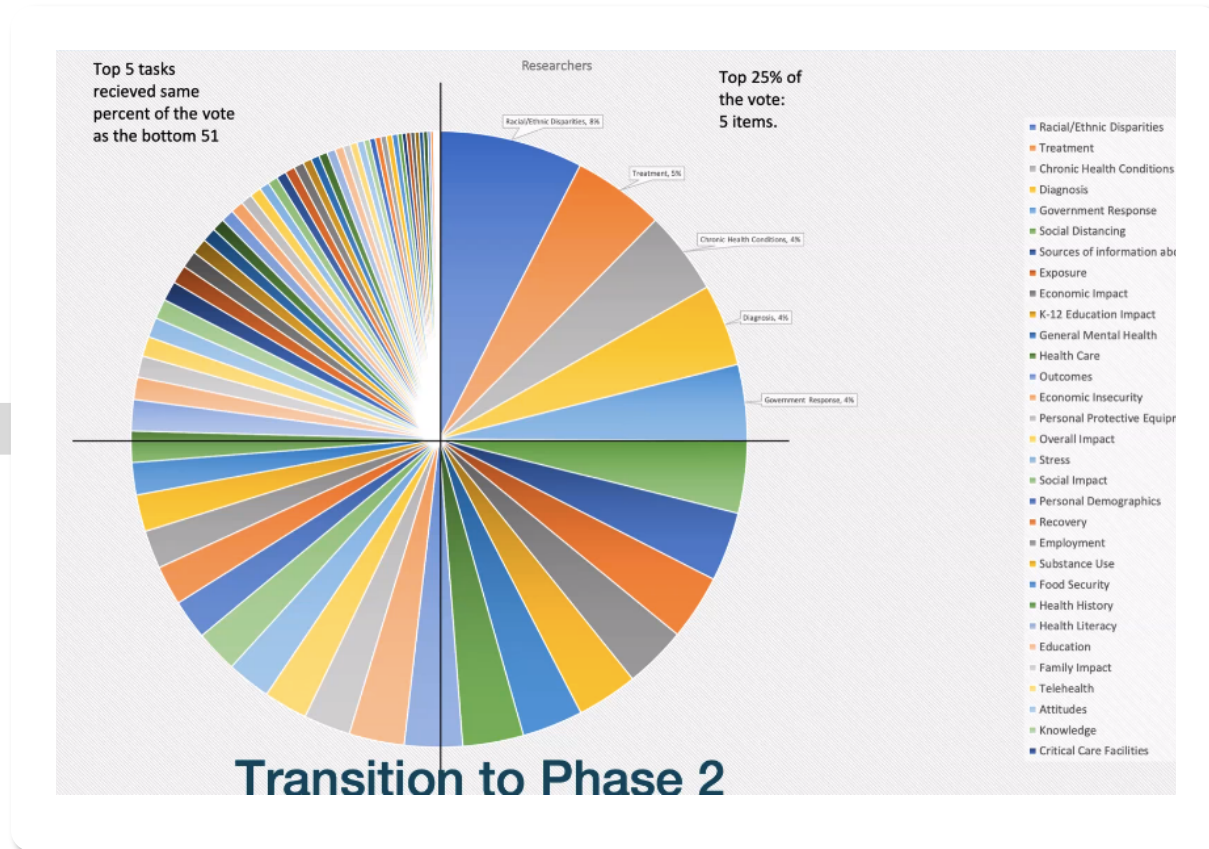
Credit: PhenX COVID Crowdsourcing

Analyze Feedback

- Segment results into 3 sections
- Top Tasks (top 25%)
- Middle Tasks (middle 50%)
- Tiny Tasks (bottom 25%)

Areas represent the value hierarchy in this space.

Top Priorities Discovery Framework: Improve

Treatment

80	Diagnosis
70	66	Recovery

80											
70	66										
54	54	51									
43	53	39	37								
42	36	40	30	45							
19	17	16	21	37	63						
10	10	13	6	32	46	53					
10	6	12	9	15	33	33	40				
25	22	21	21	20	21	20	23	46			
57	50	46	30	26	44	20	21	29	41		
51	43	42	29	23	45	21	20	18	29	67	
52	49	38	30	25	30	10	10	18	34	61	57
37	53	35	36	38	24	12	10	4	20	36	34	45
31	44	27	33	33	18	10	13	6	19	30	29	41	83

Diagnosis · Recovery · Outcomes · Exposure · Personal Protective Equipment · Social Distancing · Sources of information about COVID-19 · Government Response · Community Access · Critical Care Facilities · Telehealth · Health Care · Health History · Chronic Health Conditions

Category	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23	Q24	Q25	Q26	Q27	Q28	Q29	Q30	
Race, Ethnicity, and Demographics	84	0	1	3	0	3	1	1	4	1	8	1	7	7	3	2	3	3	2	3	1	4	10	3	10	9	0	5	8	5	
Socioeconomic Impacts	6	1	1	70	0	85	5	2	8	2	68	3	9	75	17	21	0	1	7	13	0	9	31	20	18	20	1	17	16	6	
Personal Risk Factors	1	1	34	14	4	0	7	0	34	9	3	2	24	9	48	8	72	22	57	56	13	52	37	11	17	20	14	18	32	8	
Mental Health	0	1	0	1	5	0	1	0	1	76	9	4	37	0	12	23	2	39	1	0	2	0	11	11	38	41	0	40	29	2	
COVID-19 Information and Sources	0	2	3	3	15	1	5	87	41	1	1	8	11	0	4	10	1	1	2	18	24	24	1	45	6	0	23	9	3	56	
Treatment, Outcomes, and Medical History	0	86	52	0	67	2	72	1	3	2	2	73	3	0	7	27	13	25	22	1	51	1	2	1	53	2	3	14	
77%	92.31%	94.51%	94.51%	76.92%	73.63%	93.41%	79.12%	95.60%	82.42%	83.52%	74.73%	80.22%	67.03%	82.42%	52.75%	78.02%	79.12%	94.51%	86.81%	61.54%	82.42%	83.52%	74.73%	71.43%	41.76%	89.01%	83.52%	43.96%	67.03%	61.54%	% Clean
22.60%	7.69%	5.49%	5.49%	23.08%	26.37%	6.59%	20.88%	4.40%	17.58%	16.48%	25.27%	19.78%	32.97%	17.58%	47.25%	21.98%	20.88%	5.49%	13.19%	38.46%	17.58%	16.48%	25.27%	28.57%	58.24%	10.99%	16.48%	56.04%	32.97%	38.46%	% Dirty
54.80%	84.62%	89.01%	89.01%	53.85%	47.25%	86.81%	58.24%	91.21%	64.84%	67.03%	49.45%	60.44%	34.07%	64.84%	5.49%	56.04%	58.24%	89.01%	73.63%	23.08%	64.84%	67.03%	49.45%	42.86%	16.58%	78.02%	67.03%	13.09%	34.07%	23.08%	Magnetism

Top Priorities Discovery Framework: Improve
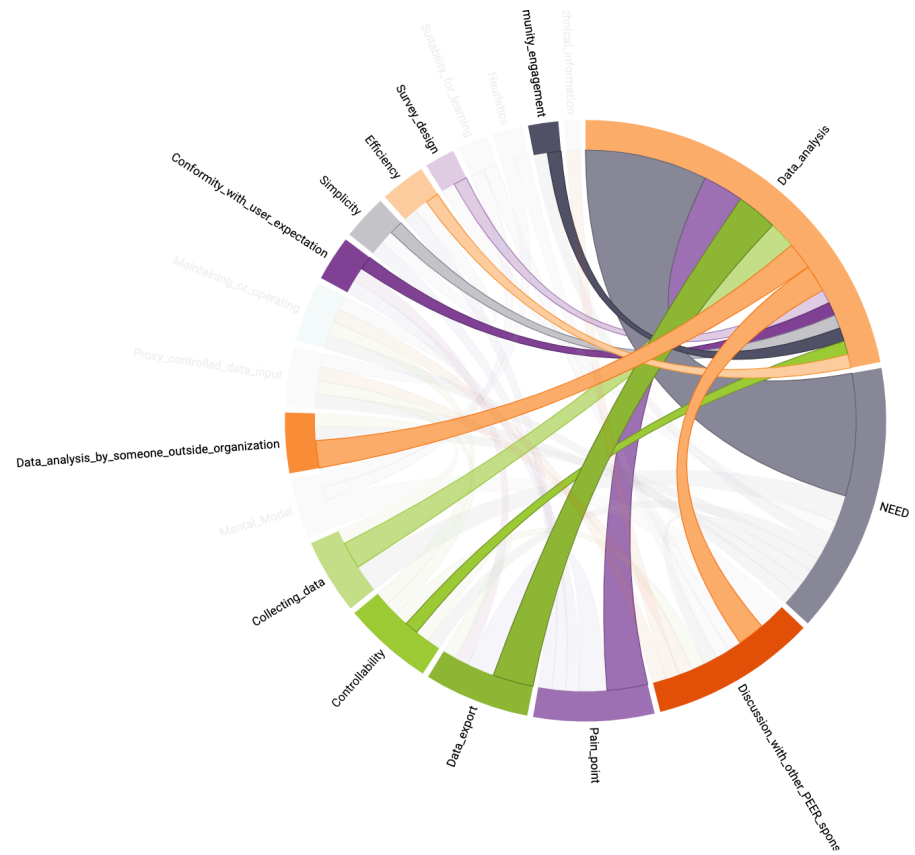
Return of Insights

Our platform:

- Simplifies process for return of results

- Improves engagement and retention

- Integrates participant insights directly with research questions

This allows us to do better research and re-engaged disenfranchised communities quickly and easily.

How do we accomplish this?

Recontact Tool

- Stay in contact with all participants, even those who are afraid of ramifications of identifying themselves for contact.

Study Results Panel

- Allows consistent return of results to improve speed of "deployment"

- Incentivizes completion of studies by hiding results until a participant has contributed required data

Study Design

Designing Your Study Strategy and Protecting Study Participants
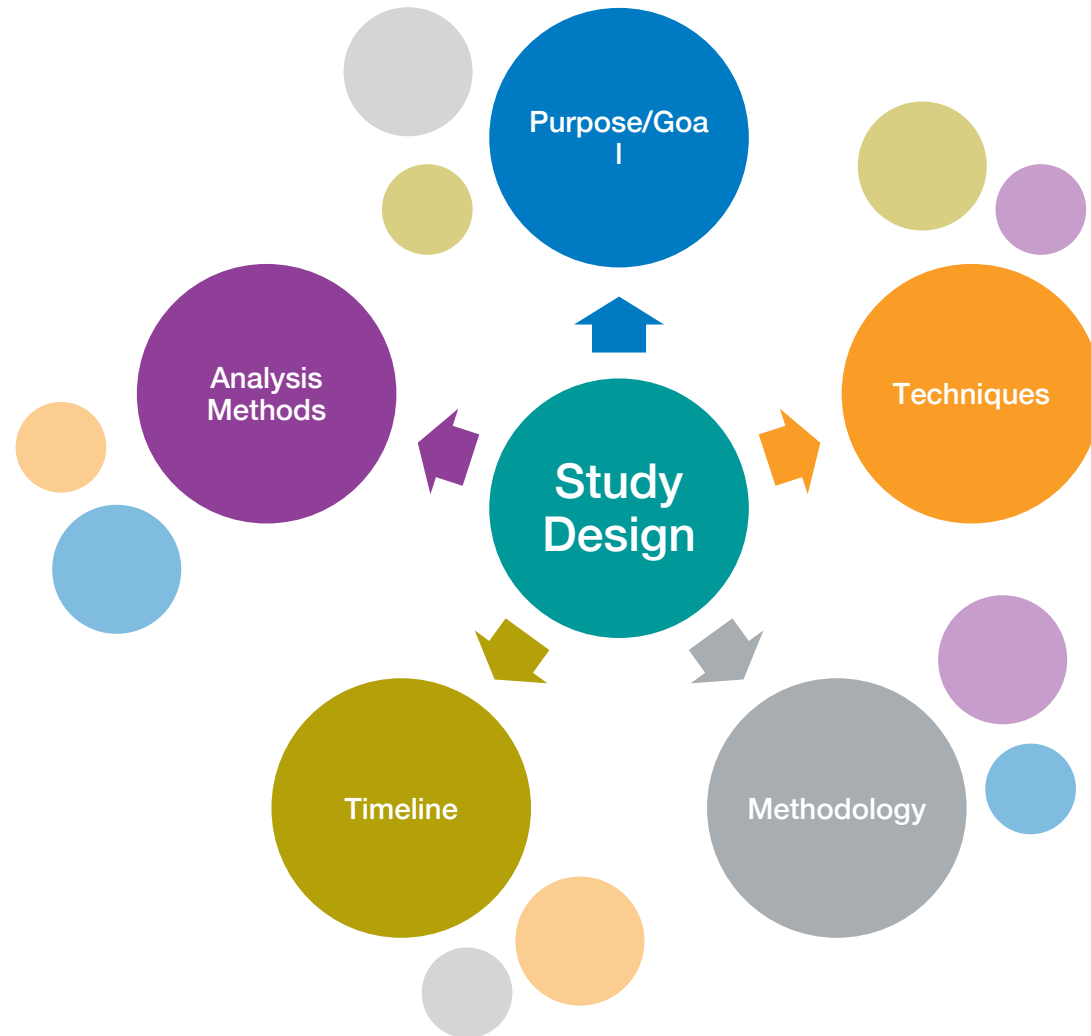
- **Genetic Alliance Bootcamp**

- **Genetic Alliance IRB**

  o **Platform approved**

  o **Registries approved**

  o **Studies approved**

- **Genetic Alliance Ethics Team**

Take Advantage of Data Collection Using the Latest Techniques and Best Practices

Survey Builder™ - in Platform Survey Creation Service

Choose from library of validated instruments

Create custom surveys

Key Features:

o Standard and complex question types

o Advanced branching and skip logic

o Set longitudinal criteria for repeat submissions

o Add images and URLs to questions for context

o Control visibility and accessibility

o Version control surveys and questions

Study Designer™ - Design Studies, Recruit participants, and Continuously Collect Data

DASHBOARD   **COLLECT DATA**   **VIEW DATA**   **SETTINGS**   **MANAGE CONTENT**

STUDY DESIGNER   SURVEY BUILDER   RECONTACT AGENT

COLLECT DATA > STUDIES

CREATE A NEW STUDY

Create a new study to target different members or to collect different types of data based on your study goals - what are you trying to learn?

CREATE STUDY

MANAGE EXISTING STUDIES

Name	Status	# Enrolled	Recontact	Close study aspects

Gate Studies with Inclusion & Exclusion Criteria

Gate with…

- Binary (yes/no) questions

- Survey responses

- Demographic details

…and more
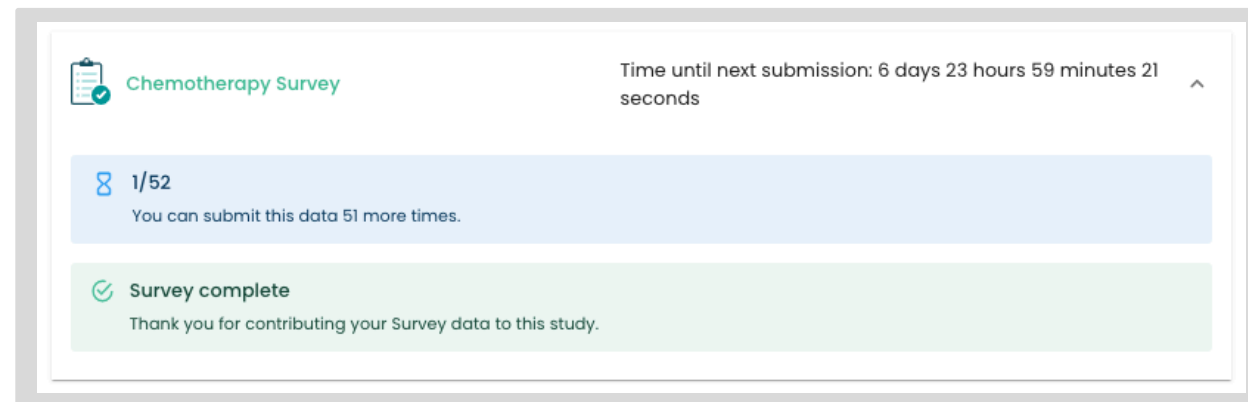
Ongoing Collection of Data from Study Participants

- Add data requests to your study all at once or at your preferred cadence

- Use Recontact Agent™ to inform study participants of new data requests

- Set longitudinal parameters to collect the same information more than once

    o Each submission is a unique entry in your analytics workbench

Recontact Agent™ - Continuous Communication While Participants Maintain Anonymity

CREATE A NEW AUDIENCE

Select filter type
Content Status

Data type (optional)

Content status

Study Member

Study Member St

Content Data Ty

Content Status

Custom Member

Customize Content

Title
COVID-Health Survey Reminder

Link
https://member.lunadna.com/contrik

Message

Dear Participant,

We noticed that your survey titled, "COVID-19 Health Survey" has been in progress for a little while.

Timing

Send on

Date
01/12/2021

Time
05:00 PM

Timing summary

Initial delivery:
1/12/2021, 5:00:36 PM
Repeats:
Never
Ends:
After 1 occurrence

Repeat

Every
0

Frequency
Days

Ends

○ Never   ○ On date
01/12/2021

⦿ After
1   occurrence

Reduced Participant Fatigue – Complete Data Once; Cross Data Set/Study Access

- Validated instruments available to all studies from Content Library in Survey Builder™

- Member-shared EHR and genetic information available to all studies

- Study Admins can grant access across studies and/or groups (e.g., registries, companies) for custom surveys

Language Support

Mental Wellness

An assessment of your anxiety and/or mental distress level relative to current situations.

In the past 7 days,

	Never	Rarely	Sometimes	Often	Always
I felt fearful	○	○	○	○	○
I felt frightened	○	○	○	○	○
It scared me when I felt nervous	○	○	○	○	○
I felt anxious	○	○	○	○	○
I felt like I needed help for my anxiety	○	○	○	○	○

Bienestar Mental

Una evaluación de su nivel de ansiedad y / o angustia mental en relación con situaciones actuales.

En los últimos 7 días

	Nunca	Raramente	A veces	A menudo	Siempre
Me sentí temeroso/a	○	○	○	○	○
Me sentí asustado/a	○	○	○	○	○
Me asustó cuando me sentí nerviosao/a	○	○	○	○	○
Me sentí ansioso/a	○	○	○	○	○
Sentí que necesitaba ayuda para mi ansiedad	○	○	○	○	○

Platform Architecture

A Framework for Discovery

Member Id: opri-9985-meh-meh

PEER

KCNT-1 Community

Group Member Id: 5648

Genetic Epilepsy in Children

Study Member Id: 789

Study Dashboard

VCF

Extract Transform Load

KCNT-1 / Biogen Workbench

Study Member Id: 789

jupyter

R

hail

+ableau

Spark MLlib

Proprietary

Reference Datasets
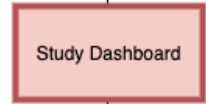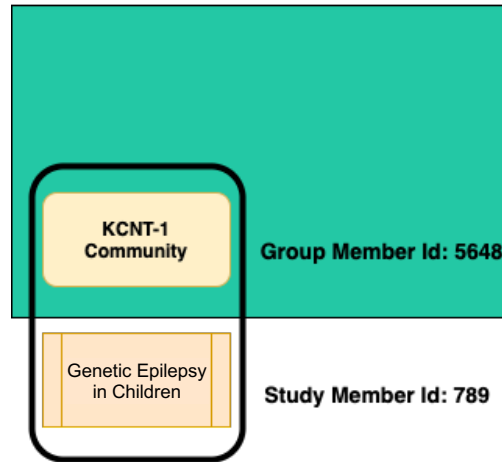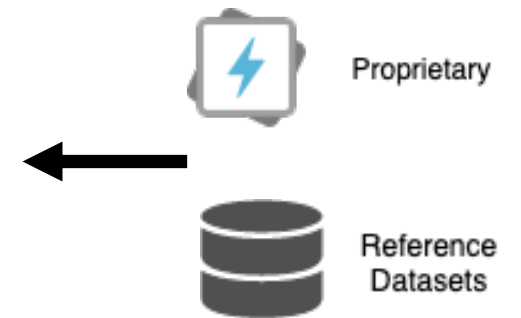
Post-Study / Post-Market Surveillance

Post Market Studies/Surveillance

- Adverse event tracking

- RWE tracking adoption, compliance

- Preparing cohorts for additional or follow-on therapies

- Reporting back to participants

- Regulatory requirements such as gene therapy registries

Thank you! Questions?

Thank You!

For additional questions or to learn more about TRAIN,
please contact TRAIN@milkeninstitute.org