

Developing a Clinical Research Registry in Autism Spectrum Disorders

Luther Kalb, PhD, MHS
Director of Informatics
Center for Autism and Related Disorders
Department of Neuropsychology
Kennedy Krieger Institute

Assistant Professor
Department of Mental Health
Johns Hopkins Bloomberg School of Public Health

Chair, National Research Consortium on MH-IDD
Center for START Services
University of New Hampshire



<https://centerforstartservices.org/mhidd-national-research-consortium>



Outline

- Review KKI-CARD clinical research registry
- Review clinic informatics infrastructure
- Review study of caregiver consent to the registry

Center for Autism and Related Disorders

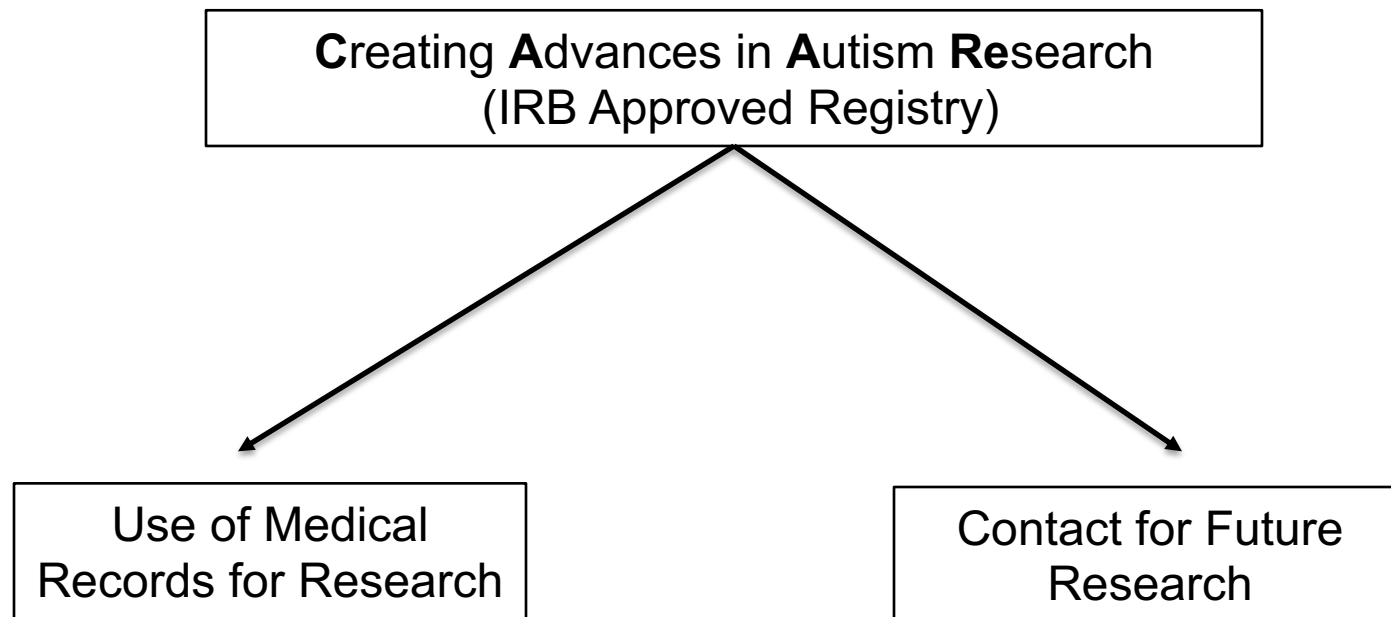


- Large, multidisciplinary ASD clinic located in Baltimore, MD
- >2000 Patients per year
- Diagnostic and Treatment
- Research, Education, Outreach



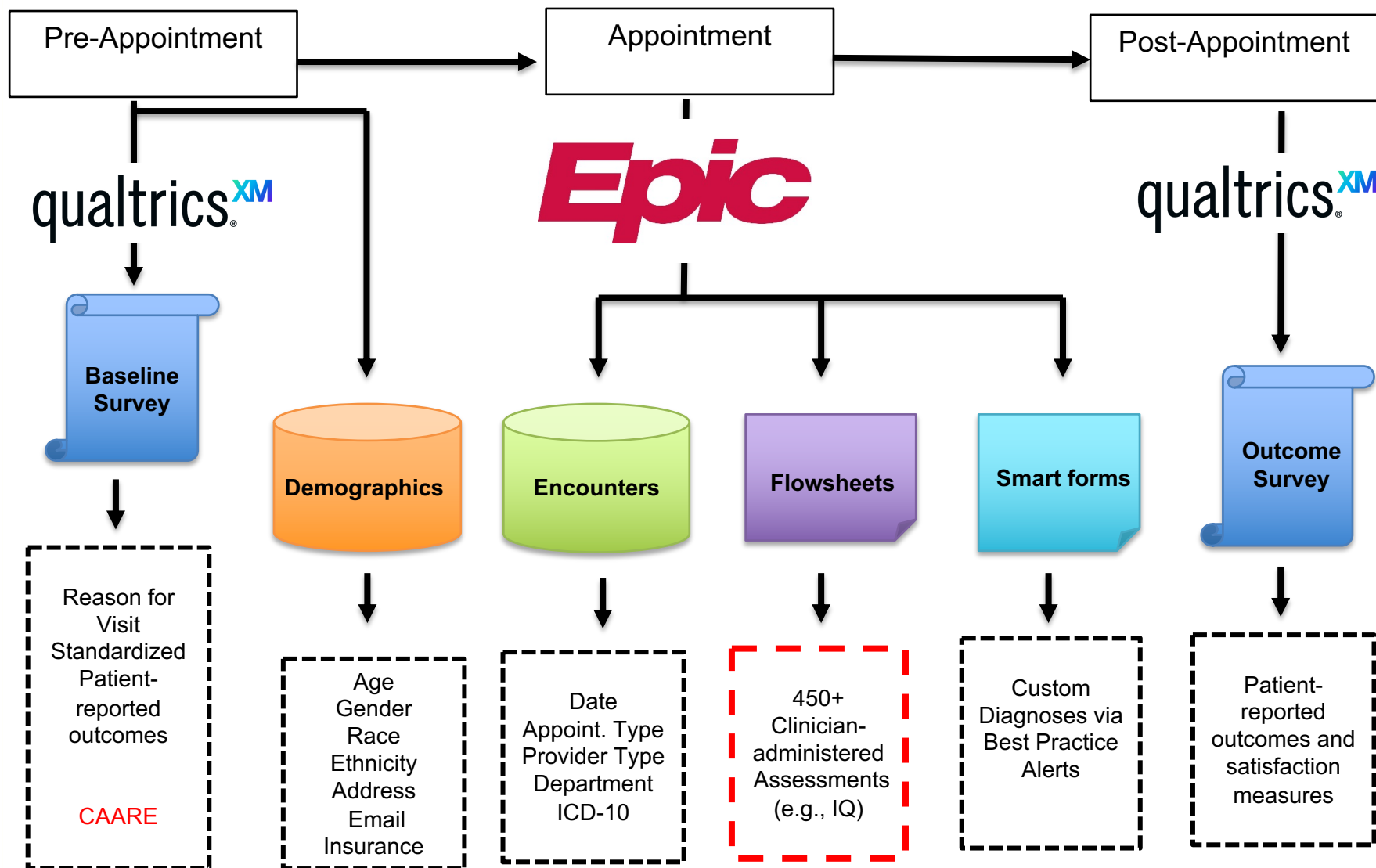
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Research Registry



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The Quantified Visit



Examples of registry research

**Journal of
& Developmental
Behavioral Pediatrics**
Official Journal of the Society for Developmental and Behavioral Pediatrics

**AUTISM
RESEARCH**

November, 2020 | Volume 13 | Number 11



Azad, G., Dillion, E., Feuerstein, J., Kalb, L., Neely, J., & Landa, R. (2020). Quality of Life in School-Aged Youth Referred to an Autism Specialty Clinic: A Latent Profile Analysis. *Journal of Autism and Developmental Disorders* (2020): 1-12.

Hong, J. S., Singh, V., Kalb, L., Ashkar, A., & Landa, R. (2021). Replication study of ADOS-2 Toddler Module cut-off scores for autism spectrum disorder classification. *Autism Research*, 14(6), 1284-1295.

Kalb, L., Jacobson, L., Zisman, et al. (2019) Interest in Research Participation among Caregivers Raising a Child with a Neurodevelopmental Disability. *Journal of Autism and Developmental Disorders*.

Kalb, L., Freedman, B., Foster, C., Menon, D., Kisfy, L., Landa, R., & Law, P (2012). Determinants of Appointment Attendance at an Outpatient Pediatric Autism Clinic. *Journal of Developmental and Behavioral Pediatrics* 33 (9), 685-697.



Azad, G., Holingue, C., Pfeiffer, D., Dillon, E., Reetzke, R., Kalb, L., et al.. (2021). The influence of race on parental beliefs and concerns during an autism diagnosis: A mixed-method analysis. *Autism*, 13623613211044345.



Interest in Research Participation Among Caregivers of Children with Neurodevelopmental Disorders

L. Kalb^{1,2,4} · L. Jacobson^{1,3} · C. Zisman¹ · E. Mahone^{1,3} · R. Landa^{2,3} · G. Azad^{2,4} · D. Menon² · V. Singh² · A. Zabel^{1,3} · A. Pritchard^{1,3}

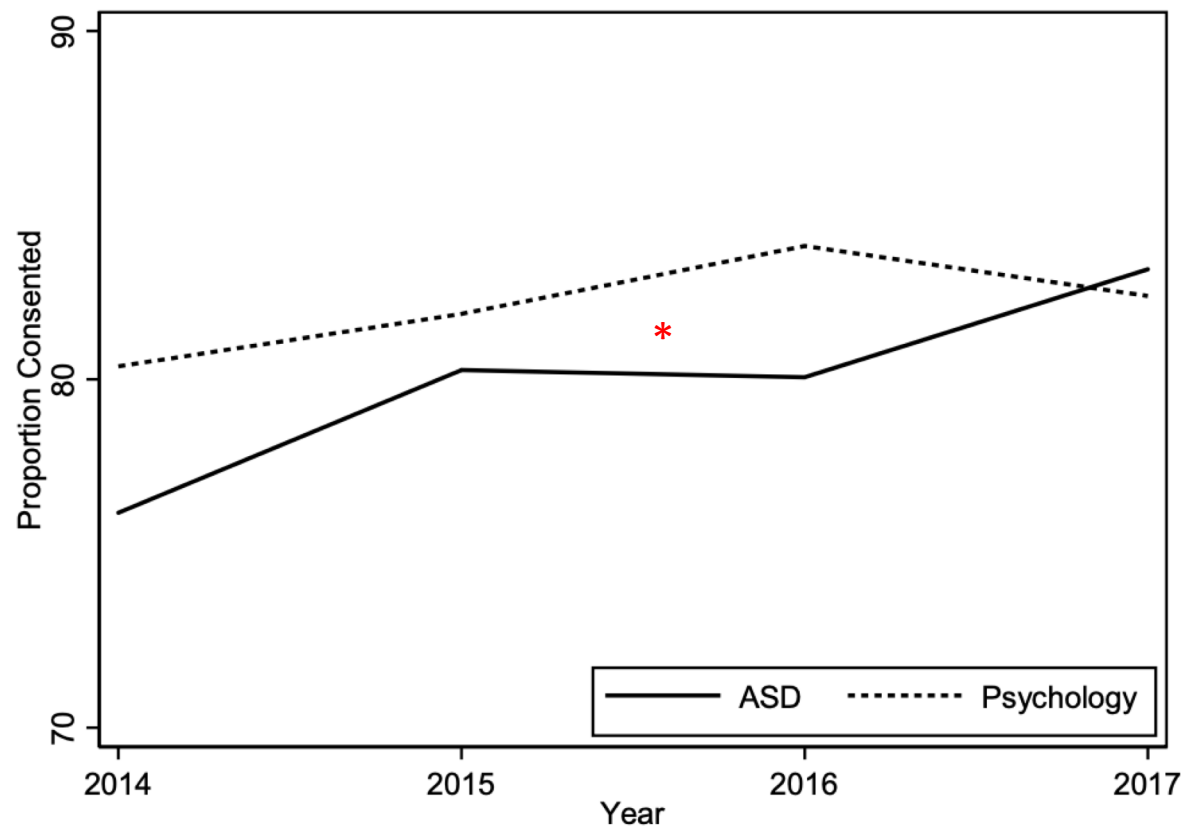
- The goal of this study was to: 1) examine caregiver agreement to hear about research opportunities by joining a local clinical research registry; 2) factors related to consent.
- CARD (N=5228) and Neuropsychology (N=5040) clinics were included



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Consent for Contact

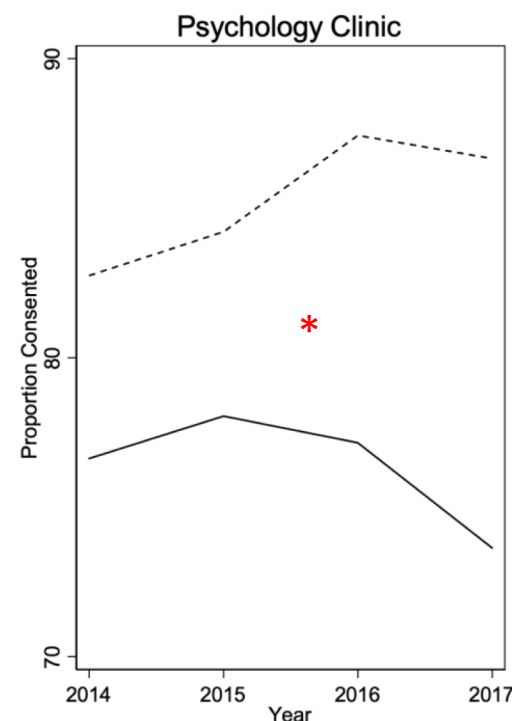
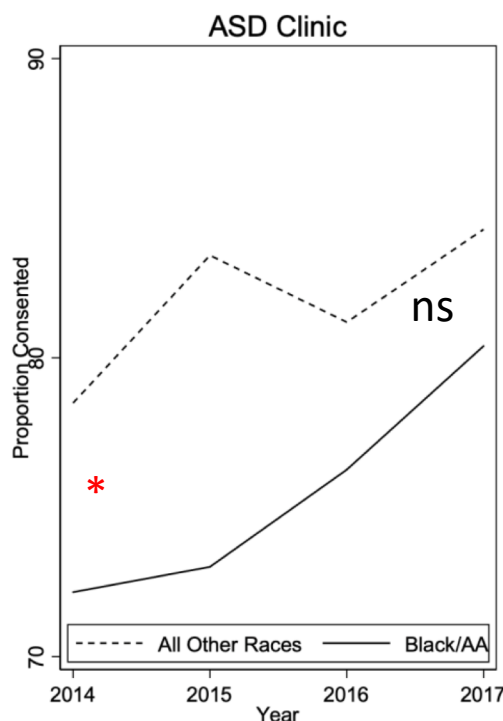
- Overall, 80% of caregivers consented
- Significant increase in CARD between 2014-2017



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Factors related to consent

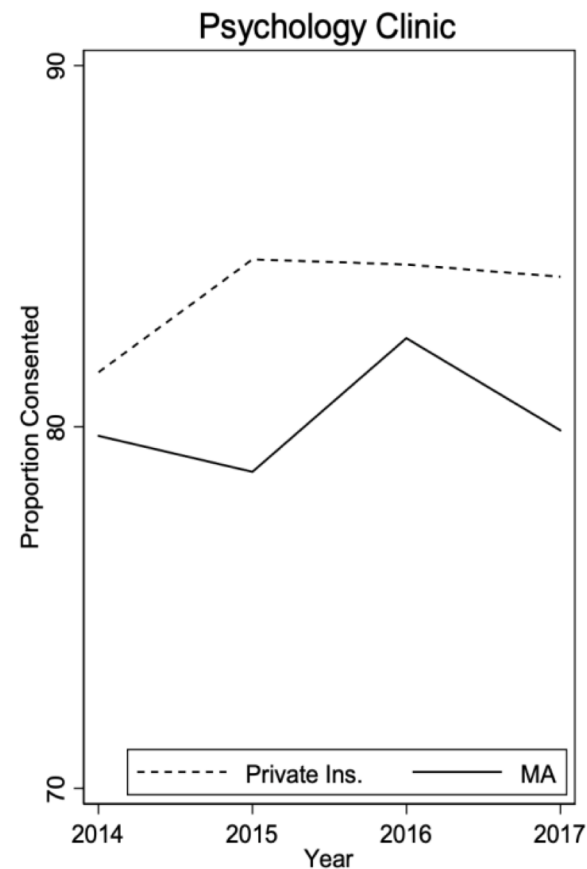
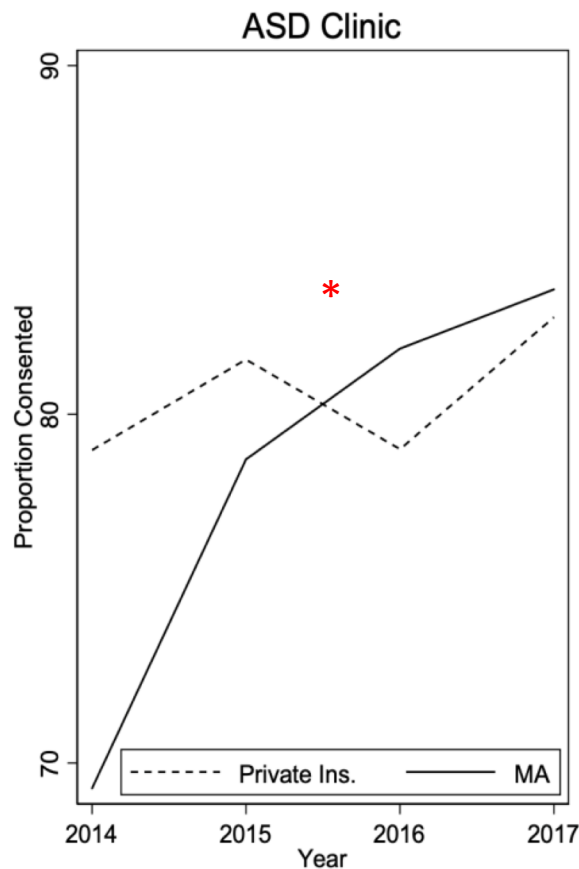
- Factors associated with providing consent:
- Race: Black/AA < All other*
- > Parent-reported Mental Health Symptoms/Sleep Problems in both clinics
- Fewer days until appointment
- Non-Significant: Informant-Type, IQ or ASD Severity, Distance to clinic, Parental Education level



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Factors related to consent II

- Significant insurance x clinic interaction



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Summary

- Pre-appointment online consent can be obtained at fairly high levels (80%+).
 - 98% of those who agree to be contacted agree to allow for consent to the EMR for research (data not shown)
- Consent is not equivalent across populations
- Recruitment registry is useful in it's own right, however the clinical data will be useless unless the EMR system has been designed

Thank You!

Contact: kalb@kennedykrieger.org





Thompson Center
University of Missouri

Research Clinic Partnership

Nicole Takahashi, MS

December 22, 2021

Overview

- Building research infrastructure
- Database evolution
- Research core description, advantages
- Research clinic partnership
- Key elements for success



Building research infrastructure

- 2008 – The Thompson Center (TC) became a clinical site for two large national autism networks
- Most early research at the center was conducted by small fragmented research teams
- A center database was established from a legacy research registry
- **The TC database formed the foundation of our research core**



Database evolution

- Initially the TC database was only used by research staff
- The database evolved to incorporate clinic workflows and electronic clinical data collection
- The TC database is now a high impact resource used across the center that helps to inform clinical practice



Research core

The Thompson Center research core

- 1) provides a central resource for storage and access to phenotypic data
- 2) facilitates subject recruitment for research studies
- 3) provides research-grade psychometric testing



Research core services

- Research consultation
- IRB
- Recruitment
- Research-reliable assessment
- Project management
- Data collection
- Biospecimen collection & processing
- Data entry
- Data management
- REDCap project creation
- Assist with abstract and manuscript preparation



Research core advantages

- Can sustain core group of experienced research staff
- Reduced reliance on single source of soft money
- Research core has established relationships with clinicians, knowledge of clinic workflows
- Access to shared database of phenotypic information
- Centralized targeted research recruitment
- Decreased assessment redundancy
- Streamlined pipeline from clinic to research



Research clinic partnership

Research collaboration with clinic is mutually beneficial

- Research recruitment in clinic
- Database used to create triage algorithm
- Collaboration with clinic to reduce waitlist and create expedited path to evaluation
- Focus on early screening by integrating into pediatric practice
- Research may identify at risk children and facilitate appropriate referrals



Key elements for success

- Leadership support, value added to center
- Nurture relationship between clinic and research
- Critical mass of funded research studies
- Establish career path to retain talented research staff
- Cross-training of research staff on diverse projects
- Clinician on each study research team
- Database



CADB REDCap Implementation: Integrating Research & Clinic

Deanna Swain, Ph.D.



Please complete the survey below.

Thank you!

Send Surveys to Participants

1) Name

2) Would you like to participate in our survey?

☐ Yes

☐ No

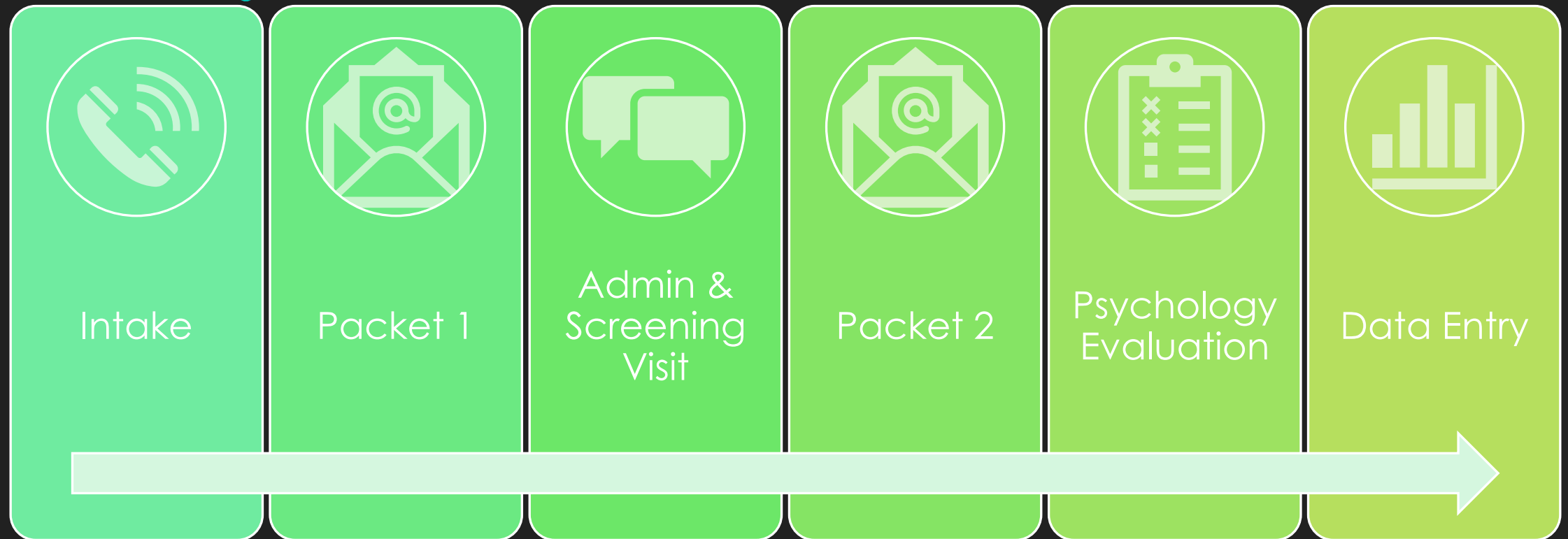
Submit

Build Online Databases

Save Data in a Secure and HIPAA Compliant Environment

	A	B	C	D
1	record_id	name	survey	survey_complete
2	1	Participant 1	1	2
3	2	Participant 2	1	2
4	3	Participant 3	1	2
5	4	Participant 4	1	2
6	5	Participant 5	1	2
7	6	Participant 6	1	2
8	7	Participant 7	1	2
9	8	Participant 8	1	2
10	9	Participant 9	1	2
11	10	Participant 10	1	2
12				

CADB Clinic & REDCap Flow



Intake Process

Old → New

NEW PATIENT INTAKE FORM

New Patient Intake

 Adding new Record ID **2021739**

Event Name: **Intake**

Record ID

2021739

Date of call

* must provide value



12-16-2021



Today

M-D-Y

CADB employee initials



DMS

(e.g., Jane Jill Doe = JJD)

Is an interpreter needed for services?

* must provide value



☒ Yes

☐ No

reset

What language did the caller speak?



Spanish

REMINDER: Please inform family that all visits will be in-person.

Patient Information

Patient first name

* must provide value



Patient preferred name



(if different from first name)

Patient middle name

* must provide value



If no middle name, just add a space.

Patient last name

* must provide value



Patient date of birth

* must provide value



MM-DD-YY



M-D-Y

Patient age at time of intake (MONTHS)



View equation

CADB Background History Form



Survey Queue

CADB New Patient Next Steps



cadb@nyp.org <redcapproject@med.cornell.edu>

3:14 PM



To: Deanna Swain

Dear new CADB family,

Thank you for completing the required CADB forms. We will be in touch if anything is missing or if we need additional documents. Our team will process your packet in the order it was received. In the meantime, we wanted to provide you with some additional information regarding what to expect next.

Insurance Clearance: You may receive a call from one of our patient finance representatives to review your plan benefits for our specialty services. If you have any out of pocket expenses, this will be explained during this phone call.

Screening Appointment: You will then receive a call to schedule your screening appointment with our Social Worker. This screening appointment will help us gather additional information regarding how CADB can best help PIPED DATA.

Please note, all of the information you provided in the packet may not be reviewed for several months. CADB does not provide ongoing mental health therapy or crisis intervention services. If you or PIPED DATA has mental health concerns, please contact a licensed mental health care provider in your area for advice or treatment options.

If PIPED DATA is experiencing a psychiatric emergency, please contact 911 or go to the nearest emergency room.

Please do not reply to this email, rather direct any questions or concerns to us by telephone at 914-997-5848 option #1.

We look forward to seeing you!

Packet 1

- Background History Form
- ASD Questionnaire
 - M-CHAT
 - SRS-2 Pre-school
 - SCQ-Lifetime
- Additional Paperwork
- Missed Appointment Policy
- Psychiatry Addendum

Thank you!

Administration Team

- Add patient to EPIC
- Create referral for screening visit
- Verify benefits with family
- Schedule screening visit

https://redcap.ctsc.weill.cornell.edu/redcap_protocols/redcap_v11.1.9/index.php?pid=3696&route=AlertsController:setup&log=1&pagenum=3&filterBeginTime=&filterEndTime=

Applications

- Project Dashboards
- Alerts & Notifications**
- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- Customize & Manage Locking/E-signatures
- Data Quality
- API and API Playground
- External Modules
- Request to copy current project
- REDCap Additional Services Request

Reports

- Psychology Evaluation (ECDC/School/Adult) Tracking Form
- Psychology Evaluation (CARE Clinic) Tracking Form
- Consent Tracking
- Psychiatry Tracking
- ABAS-3 Caregiver Report 0-5 Years FIX ERROR
- DASCA tracking
- Lisa packet processing
- Intake overview
- Psychiatry Report-Anna's Patients
- Research and Clinic Families
- 1) Dev Peds
- 2) Mullen Check
- 3) chris_rpt
- 4) abas adult

External Modules

- Multilingual Data Dictionary Support

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature
- Contact REDCap administrator

Notification Log
(in ascending order by time sent)

Displaying 201 - 220 of 220

Notification send time	Alert
11/29/2021 8:02pm	#1 (A-3)
11/29/2021 9:27pm	#1 (A-3)
11/30/2021 11:14am	#1 (A-3)
11/30/2021 9:42pm	#1 (A-3)
12/01/2021 4:20pm	#1 (A-3)
12/02/2021 11:28am	#1 (A-3)
12/03/2021 1:06pm	#1 (A-3)
12/03/2021 6:37pm	#1 (A-3)
12/05/2021 11:25am	#1 (A-3)
12/05/2021 5:20pm	#1 (A-3)
12/07/2021 9:24am	#1 (A-36)
12/10/2021 5:22pm	#1 (A-36)
12/14/2021 2:52pm	#1 (A-36)
12/14/2021 3:07pm	#1 (A-36)
12/15/2021 11:32am	#1 (A-36)
12/15/2021 7:38pm	#1 (A-36)
12/16/2021 5:59pm	#1 (A-36)
12/17/2021 6:18pm	#1 (A-36)
12/17/2021 11:16pm	#1 (A-36)
12/18/2021 3:02pm	#1 (A-36)

View Notification - Alert #1 (Unique Alert ID: A-36)

From: dms4001@med.cornell.edu

To: cadb@nyp.org

Subject: New CADB Patient Paperwork Complete

Message: Hello,
The initial paperwork for 2021739 has been submitted electronically via REDCap. Please click here to access the participant's additional paperwork: [Additional Paperwork](#)

Thank you.

Close

12/16/2021 5:59pm	#1 (A-36)	2021678 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
12/17/2021 6:18pm	#1 (A-36)	2021708 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
12/17/2021 11:16pm	#1 (A-36)	2021721 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
12/18/2021 3:02pm	#1 (A-36)	2021718 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
		2021734 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
		2021735 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
		2021737 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
		2021675 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
		2021689 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	
		2021739 - Intake	cadb@nyp.org	New CADB Patient Paperwork Complete	

Screening Appointment

- Completed by Social Worker
- Review and consent family
- Complete M-CHAT follow-up questions if needed

CADB Paperwork for Psychology Evaluation



cadb@nyp.org <redcapproject@med.cornell.edu>



3:40 PM

To: Deanna Swain

Dear CADB family,

Thank you for scheduling your assessment for Test with our Psychology team for ~~12-29-2021~~. In order for us to best serve you, we will need additional information which can be completed at the link below.

Please complete these forms as soon as possible but no later than ~~12-15-2021~~. If we do not receive your completed questionnaires by this date, we may need to reschedule your appointment.

You may open the survey in your web browser by clicking the link below:

[Autism Impact Measure \(AIM\)](#)

If the link above does not work, try copying the link below into your web browser:

https://redcap.ctsc.weill.cornell.edu/redcap_protocols/surveys/?s=tPeortt5ILSiF6m7

This link is unique to you and should not be forwarded to others.

Scheduling Psychology Evaluation

Best Case Scenario

- ✓ AIM
- ✓ Past Evaluations
- ✓ CBCL ★
- ✓ ABAS ★
- ✓ RBS-R
- ✓ DASCA

Data Collection Instruments

Add new instrument:

- [Create](#) a new instrument from scratch
- [Import](#) a new instrument from the official [REDCap Instrument Library](#) ?
- [Upload](#) instrument ZIP file from another project/user or [external libraries](#) ?

Survey options:

- [Survey Queue](#) ✓
- [Survey Login](#)
- [Survey Notifications](#)

Past Evaluations

Does Test have a current Individualized Family Service Plan (IFSP) or Individualized Education Program (IEP)?

☐ Yes ☐ No

* must provide value

u

Does Test have a current 504 Plan?

☐ Yes ☐ No

* must provide value

u

Copies of report cards

[Upload file](#)

You indicated that Test has a previous diagnosis of ASD. Please upload a copy of the report (medical professional or psychologist).

[Upload file](#)

Has Test previously completed a psychological evaluation?

☐ Yes ☐ No

* must provide value

u

Has Test previously completed a psychiatric evaluation?

☐ Yes ☐ No

* must provide value

u

Psychiatric hospitalization discharge paperwork

[Upload file](#)

Genetics Testing and Reports

[Upload file](#)

Neurology evaluations

[Upload file](#)

Additional file:

[Upload file](#)

Additional file:

[Upload file](#)

Worst Case Scenarios

1. Family gets reminder email 5 days after 1st email received
2. Scheduler receives 2-week warning email
3. Psychology technicians receive 1-week warning email
4. Family fills out forms on iPad during in-person visit

CADB Appointment Tracking

Packet 2 Recipient

(CONFIRM THAT THE RECIPIENT MATCHES THIS NAME: Deanna Swain)

(update as needed)

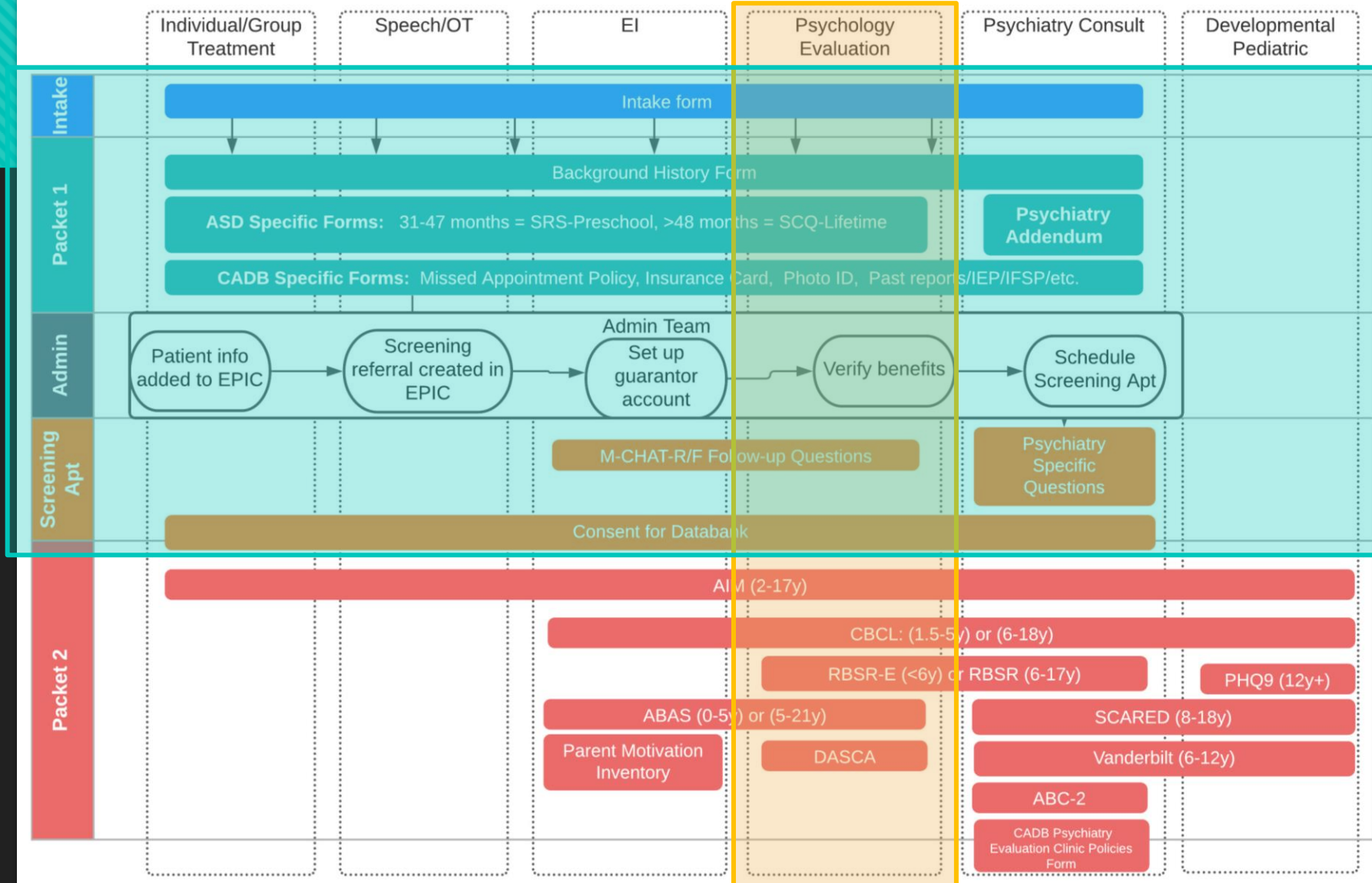
Packet 2 Email

(CONFIRM THAT THE EMAIL MATCHES THIS ADDRESS: dms4001@med.cornell.edu)

(update as needed)

Appointment	Appointment Date	Send Packet?
Psychology Evaluation	1st Time Clinic: <div style="display: flex; align-items: center;"> <div style="border: 1px solid #ccc; padding: 2px; margin-right: 5px;">ECDC (< 6 years)</div> <div style="margin-left: 10px;"> <div style="border: 1px solid #ccc; padding: 2px; display: flex; align-items: center;"> <div style="flex: 1;">12-29-2021</div> <div style="width: 20px; text-align: center; font-size: 0.8em;">31</div> <div style="margin-left: 5px;">M-D-Y</div> </div> <div style="border: 1px solid #ccc; padding: 2px; margin-top: 2px;">Sophy Kim</div> </div> </div>	<p style="font-size: 0.8em; color: #007bff; margin: 0;"><u>DASCA Forms:</u></p> <div style="margin-bottom: 5px;"> <div style="border: 1px solid #ccc; padding: 2px; display: flex; align-items: center;"> <div style="flex: 1;">7</div> <div style="width: 20px; text-align: center; font-size: 0.8em;">v</div> </div> </div> <div> <div style="border: 1px solid #ccc; padding: 2px; display: flex; align-items: center;"> <div style="flex: 1;">2</div> <div style="width: 20px; text-align: center; font-size: 0.8em;">v</div> </div> </div> <div style="margin-top: 5px;"> <input checked="" type="radio"/> Yes <input type="radio"/> No </div> <p style="text-align: right; font-size: 0.7em; color: #888;">reset</p>
	CARE	<p style="font-size: 0.8em; color: #007bff; margin: 0;"><u>Status:</u></p> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;"> Incomplete - no follow-up yet </div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;"> Incomplete - no follow-up yet </div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;"> Incomplete - Daisha followed-up </div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;"> Incomplete - Psych-tech followed-up </div> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;"> Complete </div> <p style="font-size: 0.8em; color: #007bff; margin: 0;"><u>Missing Data Codes:</u></p> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;"> Unknown (UNK) </div> <div style="border: 1px solid #ccc; padding: 2px;"> Not applicable (NA) </div>

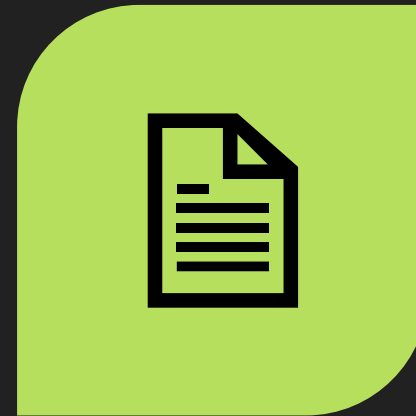
CADB REDCap Clinic Flow



Helpful Tools/Features



DASHBOARDS



REPORTS

Ways REDCap can be helpful for...

Clinicians

- Access patient survey data from anywhere
- Treatment outcome monitoring

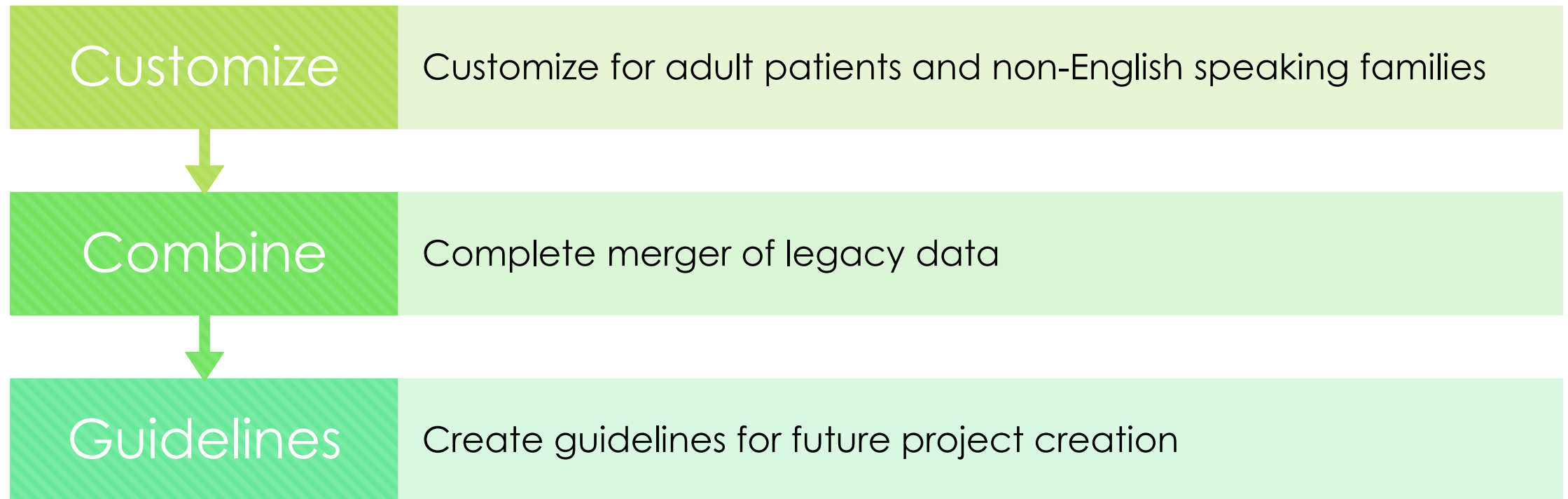
Researchers

- Item level data collected for all surveys
- Auto-scoring reduces time on back-end
- Multi-site studies can easily share data

Administrators

- Track clinician throughput
- Track clinic flow and efficiency
- Make workflow explicit

Next Steps



Acknowledgements

Steve
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Constant

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Nicole
Takahashi

All staff and
families at
CADB!