



# How to Operationalize Adaptive Sampling along with various Big Data phenotypic-neurologic-ecological-genotypic elements across a multi-site Trauma-based Prospective Data Collection, the AURORA Cooperative Agreement

BigSurv18; Barcelona, Spain; October 2018

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- Study Overview
- Protocol Design
- Adaptive Features re Big Data Elements
- Some Challenges We Wanted to Solve
  - Eligibility and Cohort Assignment
  - Event Monitoring and Incentive Payments
  - Ecological Monitoring
- The Solutions We Implemented

- Funded as the Longitudinal Assessment of Post-Traumatic Syndromes Cooperative Agreement
- Understand, prevent, and predict post-traumatic neuropsychiatric conditions
- 5-year study funded by NIH and foundations
  - University of North Carolina at Chapel Hill
- Recruitment from Emergency Departments
- Goal is to enroll 5,000 participants

Far more in-depth, multi-layered, serial data collection...



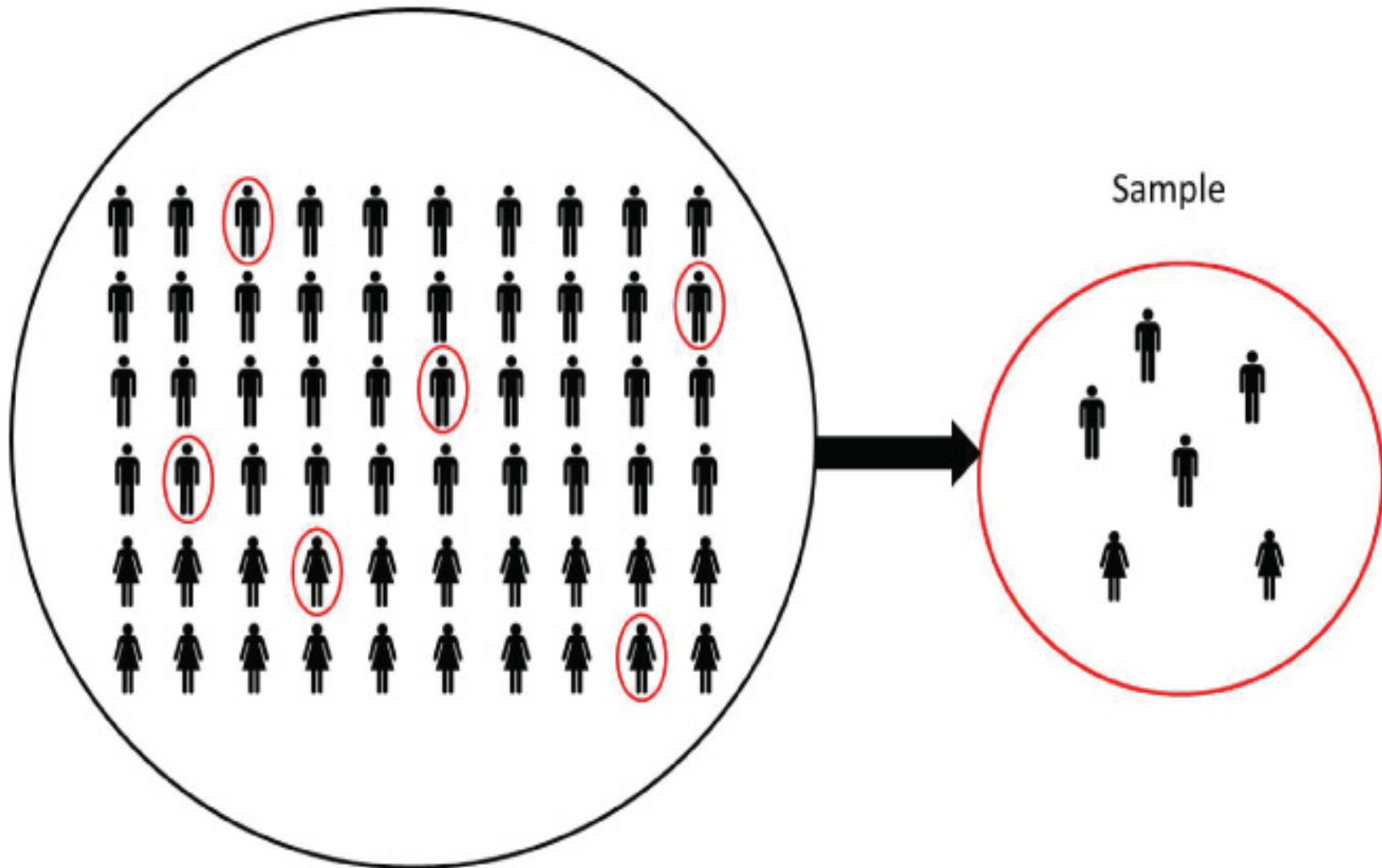
Requires a far more rapid pace of data collection...



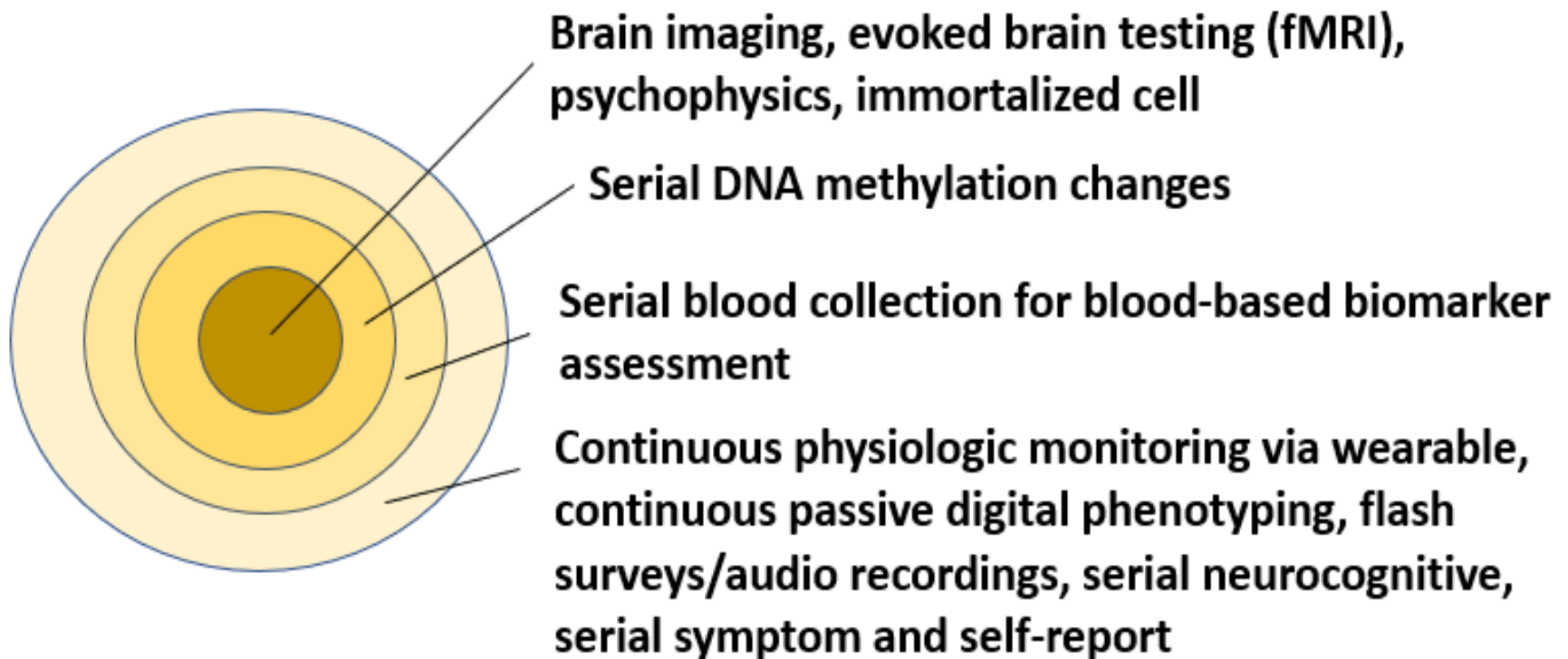
Source: UNC School of Medicine., Dr. McLean



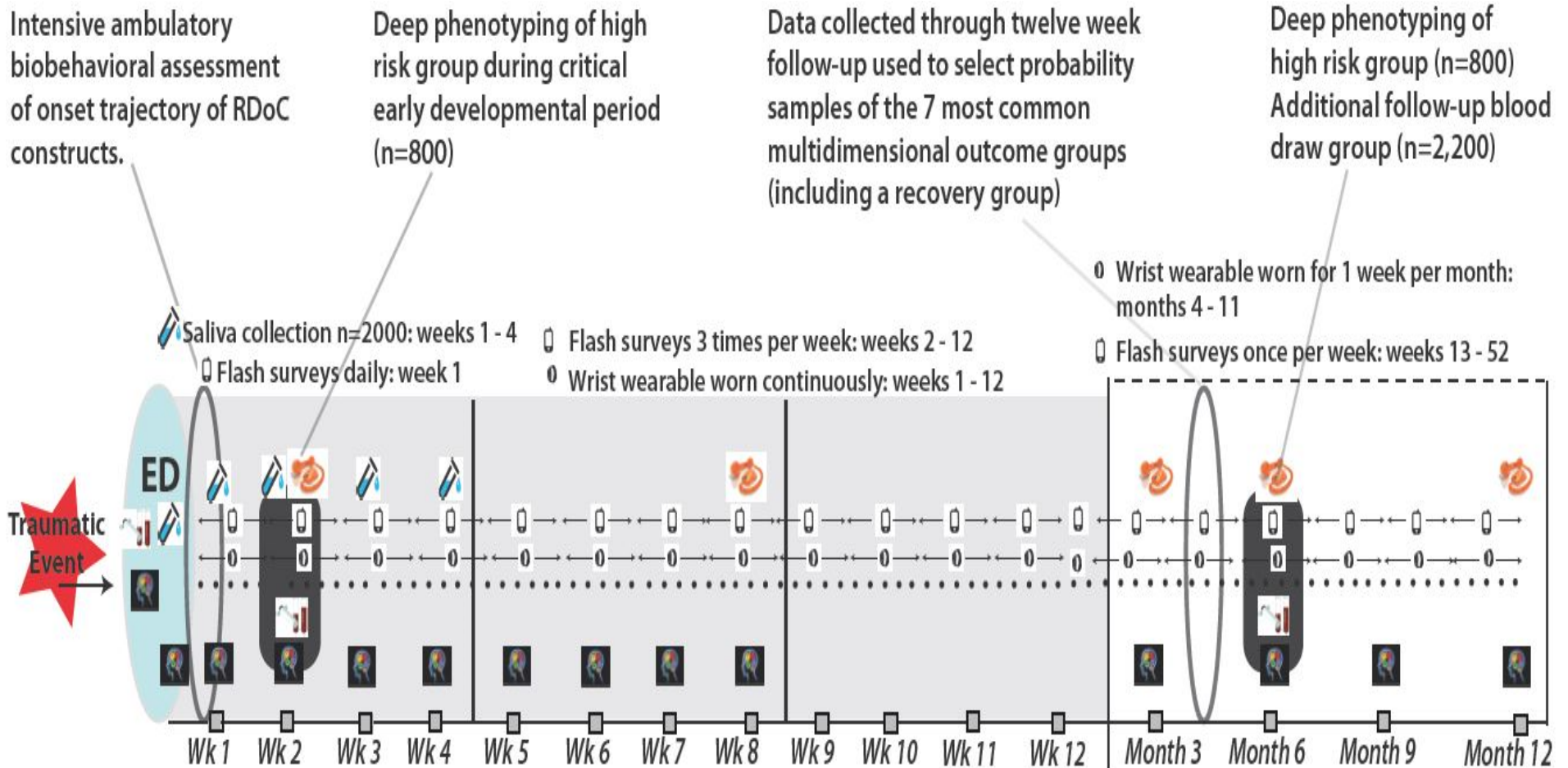
# Adaptive real-time selection for neuroimaging, blood, etc.



**AURORA:** Adaptive sampling to achieve data collection from the right study participants and the right number of study participants for each data type

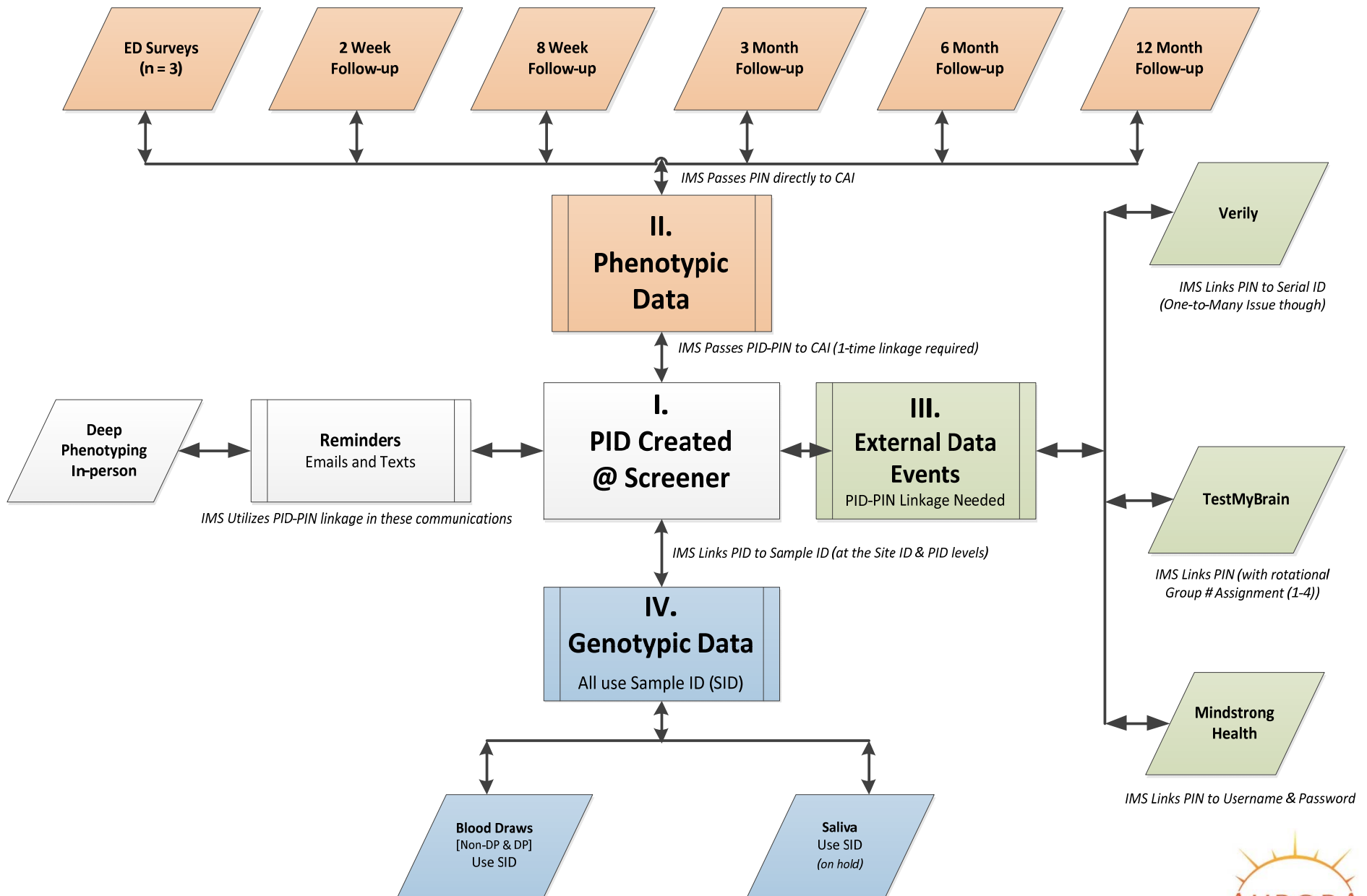


# Protocol Design



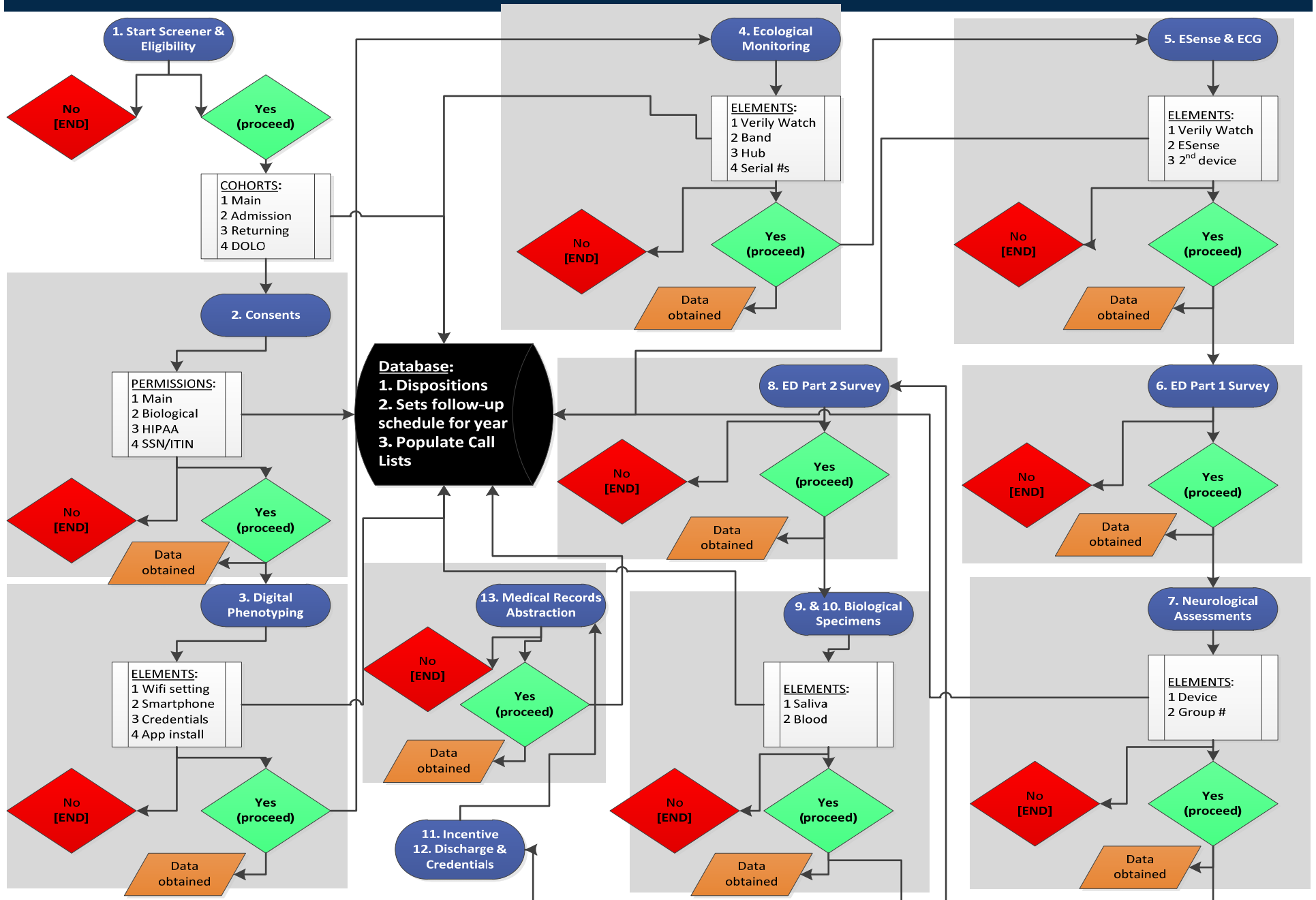
**Figure X.** Study design overview (n=5,000). = web-based neurocognitive assessment; = flash surveys of cognition and symptoms; = wrist device evaluating circadian and physiologic characteristics; = saliva collection; = blood product collection; = passive digital phenotyping = telephone/internet survey; deep phenotyping includes blood draw, fMRI, and psychophysical assessment.

# AURORA Data Flow



- Enrollment Process, a 13-step adaptive program
  - Seamless to ED User
  - Screening for Eligibility + Cohort Assignment + Willingness
  - Variables immediately available for assignments, display, groupings, adaptive sampling purposes

# Adaptive Challenge #1: Enrollment Architecture



# Adaptive Challenge #2: Event Elements

## ▪ Protocol events for weekly neurocognitive assessment

### Weekly neurocognitive assessment contact protocol for all participants (week 2 – week 9)

**Day 7 (repeated on days 13, 20, 27, 34, 41, 48, 55; text and email), 2 hours after their daily blackout period ends: IMS sends initial automated neurocognitive assessment completion request to participants. No link in text\*.**



**Day 9 (repeated on days 15, 22, 29, 36, 43, 50, 57)), 2 hours after their daily blackout period ends: IMS automated reminder to complete initial neurocognitive assessment. No link in text\***



**Day 10 (repeated on days 17, 24, 31, 38, 45, 52, 59), 2 hours after their daily blackout period ends: IMS automated reminder to complete initial neurocognitive assessment. UNC team begins phone calls to touch base and ask.**



**Midnight of study day 12 (repeated on days 19, 26, 33, 40, 47, 54, 61): IMS closes weekly neurocognitive assessment window.**

### CHALLENGES:

- Tied to participant's preferences
- Opening and closing dates
- Multi-communication channels
- Black out period
- Status codes
- Active vs. Inactive vs. Cancellation
- Incentives
- 5,000 individual schedules
- Protocol changes

computer screen rather than a smartphone screen. Therefore, as indicated, the initial texts sent to smartphone will NOT have a link to the assessment that would immediately open assessment within smartphone screen, but rather will simply remind them to complete and refer them to email instructions.

# Adaptive Challenge #2: Event Solutions

- RTI developed a sophisticated control system to support data collection **SOLUTIONS:**

- Defines
  - Houses
  - Can send
  - This system is called **AURORA**
- System data driven schedule generation
  - Event Table holds the “master shell” schedule
    - Event code
    - Day “offset” from Day 0 Enrollment
    - Hours from Blackout
    - Communication mode(s)
    - Incentive points for completion
    - Batch processing (hourly, daily)

Event	Day Offset	Last Day	Hours After Offset	Event Type ID	Via Text	Via Email	Via Phone	Active	Incentive Points	Stage	Complete Status	Assessment ID	Survey ID
NCA1	1	6	-	1	-	-	-	1	400	412	2690	1	-
NCA1 Invite (email)	1	1	2	2	-	1	-	1	0	700	1052	-	-
NCA1 Invite (text)	1	1	2	2	1	-	-	1	0	701	1052	-	-

- Web-based Information Management System (IMS) provides screens for:
  - Overall progress monitoring, reporting, and status updating
  - Designating authorized user roles and responsibilities
  - Allowing all primary data collection to commence and tracking
  - Viewing event schedules and status history
  - Incentive points earned, outstanding, and forthcoming
  - See illustrations next few slides

# Big Data Solution #1



Welcome, System Admin

Log Off

Home

Participants

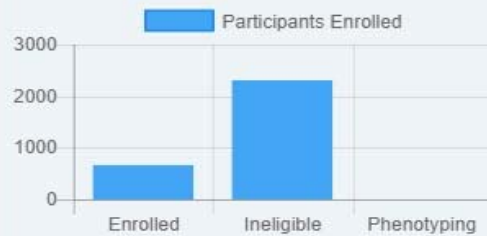
Call Lists ▾

Biologics ▾

CoC ▾

Admin

## Participants



## In-Person Sessions



## Reports

- ✓ [Overall Status Report](#)
- ✓ [Enrollment Report](#)
- ✓ [Ineligible Report](#)
- ✓ [Refusal Report](#)
- ✓ [Follow-up Rate Report](#)
- ✓ [NCA Report](#)
- ✓ [ED Report](#)

## Event Tracking



## Incentives

Participants that need to be paid today!

71

## Reloadable Cards

Participants that need a card ordered today!

3

# Big Data Solution #2

## User Account.

[Back to List](#)

**Email**

CharlieK@BigSurv18.com

**Role**

ClinicAdmin

**FirstName**

Charlie

**LastName**

Knott

**Phone**

919-555-5555

**Site**

RTI

**Active?**



**Password**

**Confirm password**

Register

# Big Data Solution #3

## Participants

New Screener

	Site	PID	PIN	First Name	Last Name	Gender	Phone	Overall Status
		<a href="#">105579</a>				Male		2400 - Refusal
		<a href="#">105578</a>				Female	(C)	2700 - Enrolled
Med. Extract		<a href="#">105577</a>				Female	(C)	2700 - Enrolled
Med. Extract		<a href="#">105576</a>				Male	(C)	2700 - Enrolled
Survey		<a href="#">105575</a>						1800 - Screener Error
		<a href="#">105574</a>				Female	(C)	2700 - Enrolled
Survey		<a href="#">105573</a>				Female		1600 - Overall Status-Pendi
Med. Extract		<a href="#">105572</a>				Male	(C)	2700 - Enrolled
		<a href="#">105571</a>				Female	(C)	2700 - Enrolled
		<a href="#">105570</a>				Male		2400 - Refusal

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# Big Data Solution #4

## Follow-up Call List

Hide dialed PID

		Dialed	Dialed By	PID	Best Call Time	Blackout Period	Reason to Call	Close Date	Last C
	Dial	<input type="checkbox"/>		<a href="#">103993</a>	TUE 05:00 PM - 11:59 PM	09:00 AM - 05:00 PM	NCA9 Reminder (Phone)	2018-09-11	1225 - Num disconnect
	Dial	<input type="checkbox"/>		<a href="#">104207</a>		08:00 AM - 06:00 PM	NCA8 Reminder (Phone)	2018-09-11	1221 - Left
		<input checked="" type="checkbox"/>		<a href="#">104394</a>	TUE 07:00 AM - 07:00 PM	10:00 PM - 07:00 AM	NCA7 Reminder (Phone)	2018-09-11	1221 - Left
	Dial	<input type="checkbox"/>		<a href="#">104589</a>	TUE 03:00 PM - 05:00 PM	11:00 PM - 07:00 AM	NCA6 Reminder (Phone)	2018-09-11	1225 - Num disconnect
		<input checked="" type="checkbox"/>		<a href="#">104579</a>	TUE 09:00 AM - 05:00 PM	07:00 PM - 05:00 AM	NCA6 Reminder (Phone)	2018-09-11	1221 - Left
	Dial	<input type="checkbox"/>		<a href="#">104800</a>	TUE 07:00 PM - 10:00 PM	09:00 AM - 07:00 PM	NCA5 Reminder (Phone)	2018-09-11	1221 - Left
		<input checked="" type="checkbox"/>		<a href="#">103810</a>	TUE 09:00 AM - 1:00 PM	09:00 PM - 07:00 AM	8 Week Follow-Up Reminder (Phone)	2018-09-11	1221 - Left
		<input checked="" type="checkbox"/>		<a href="#">105368</a>	TUE 07:00 PM - 11:00 PM	10:00 PM - 08:00 AM	NCA2 Reminder (Phone)	2018-09-11	1221 - Left
		<input checked="" type="checkbox"/>		<a href="#">105344</a>	TUE 06:00 PM - 12:00 AM	01:00 AM - 10:00 AM	NCA2 Reminder (Phone)	2018-09-11	1221 - Left
		<input checked="" type="checkbox"/>		<a href="#">105473</a>	TUE 11:00 AM - 03:00 PM	10:00 PM - 08:00 AM	NCA1 Reminder (Phone)	2018-09-11	1001 - Stag

# Big Data Solution #5



## Participant Detail

PID: [redacted] | Name: [redacted] | DOB: [redacted] | Enrollment Date: 09/01/2018 | Site: [redacted]

Contacts
Open Windows
Event History
Follow-up Notes
Payments
Appointments

Event
Emails & Texts
External Data
Other Events

Event	Open Date	Close Date	Status		Status Date	% Complete
NCA0	09/01/2018	09/01/2018	2690 - Interview Complete		2018-09-01 02:37:34	
Day 0 Status	09/01/2018	09/04/2018	2698 - Enrolled - DEX Incomplete		2018-09-01 03:18:23	100%

Date	Event Type	Status	Notes	Completed By
2018-09-01 03:18:23		2698 - Enrolled - DEX Incomplete		105395
2018-09-01 03:13:46		2781 - End of ED Part 2 SAQ		105395
2018-09-01 02:42:29		2780 - Start of ED Part 2 SAQ		105395
2018-09-01 02:42:27		2780 - Start of ED Part 2 SAQ		105395
2018-09-01 01:27:15		1001 - Stage Initiated		[redacted]
2018-09-01 01:27:15		1640 - Break-off		105395
2018-09-01 00:00:00		1700 - Missed		105395
2018-09-01 00:00:00		1700 - Missed		105395

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1
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10

Overall Status	09/01/2018	09/01/2019	2700 - Enrolled		2018-09-01 03:18:23	
Missed/Return Call (Phone)	09/02/2018	09/04/2018	2905 - Time Expired		2018-09-05 05:45:00	
NCA1	09/02/2018	09/07/2018	2690 - Interview Complete		2018-09-03 17:57:41	

# Big Data Solution #6



## Participant Detail

PID: [redacted] | Name: [redacted] | DOB: [redacted] | Enrollment Date: 09/01/2018 | Site: [redacted]

Contacts		Open Windows		Event History		Follow-up Notes		Payments		Appointments	
Scheduled Payment Date		Payment									
☑	09/01/2018	\$60.00									
Event		Open Date	Close date	Percent Complete	Date Completed	Points	Payment	Date Paid			
Day 0 Status		09/01/2018	09/04/2018		09/01/2018	1200	\$60.00	09/01/2018			
⊕	09/15/2018	\$69.50									
⊕	09/22/2018	\$0.00									
⊕	09/29/2018	\$0.00									
⊕	10/06/2018	\$0.00									
⊕	10/13/2018	\$0.00									
⊕	10/20/2018	\$0.00									
⊕	10/27/2018	\$0.00									
⊕	11/03/2018	\$0.00									
⊕	11/10/2018	\$0.00									

# Big Data Solution #7

## Specimen Collection Summary

Blood										
Saliva										
ED										
2-Week In-Person										
6-Month Blood										
6-Month In-Person										
	Collection ID	Site Name	PID	Sample ID	RUID	First Name	Last Name	DOB	Consent Date	
<input type="radio"/>	<a href="#">1308</a>		<a href="#">105626</a>	<a href="#">824-</a>					09/11/2018	270C
<input type="radio"/>			<a href="#">105625</a>						09/11/2018	270C
<input type="radio"/>	<a href="#">1307</a>		<a href="#">105607</a>	<a href="#">830-</a>					09/10/2018	270C
<input type="radio"/>			<a href="#">105605</a>						09/10/2018	160C
<input type="radio"/>	<a href="#">1303</a>		<a href="#">105584</a>	<a href="#">865-</a>					09/09/2018	270C
<input type="radio"/>	<a href="#">1304</a>		<a href="#">105581</a>	<a href="#">846-</a>					09/09/2018	270C
<input type="radio"/>	<a href="#">1302</a>		<a href="#">105578</a>	<a href="#">842-</a>					09/09/2018	270C
<input type="radio"/>			<a href="#">105577</a>						09/09/2018	270C
<input type="radio"/>	<a href="#">1306</a>		<a href="#">105576</a>	<a href="#">842-</a>					09/08/2018	270C
<input type="radio"/>	<a href="#">1301</a>		<a href="#">105574</a>	<a href="#">865-</a>					09/08/2018	270C

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