ADRC Biomarker Data Variables and Data Quality Workgroup

Co-Leads:

Kristen Russ, PhD (Indiana ADRC)

Fanny Elahi, MD, PhD (Mt. Sinai ADRC)

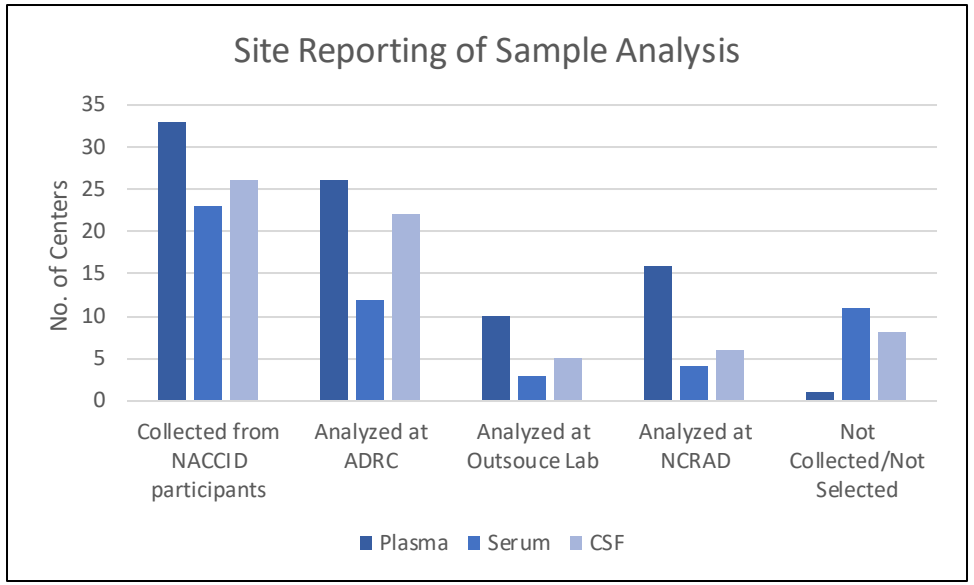
ADRC Biomarker Data Variables and Data Quality Workgroup Purpose

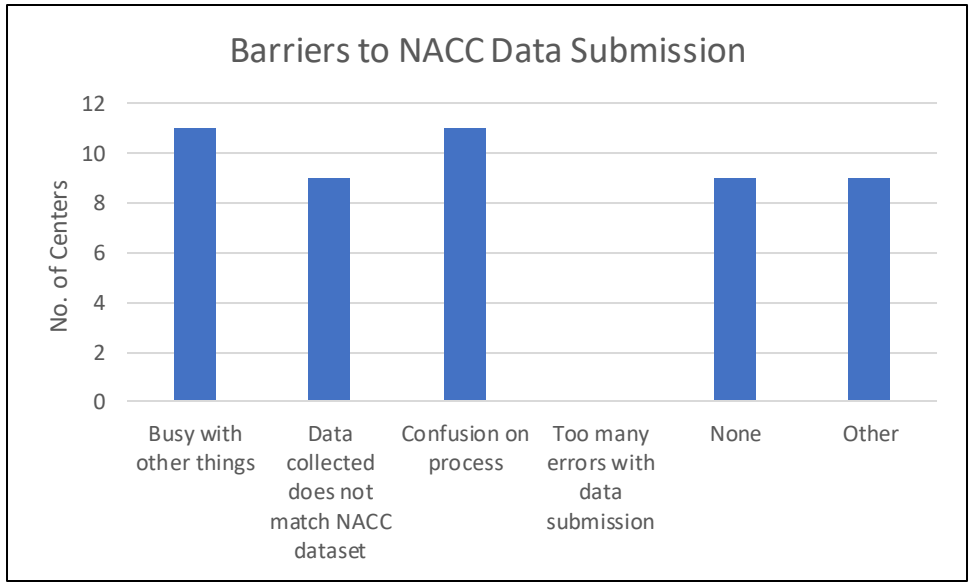
- As use of biospecimens and biomarkers in ADRD grows, it is essential to share existing data
- Storing fluid-based biomarker data alongside existing clinical data for participants at NACC is a logical choice
  - Requires development of new data fields!

<u>Workgroup Charter</u>: Determine new data fields that would be necessary as part of NACC forms to accommodate harmonization for biomarker data analyses across ADRCs

ADRC Surveys

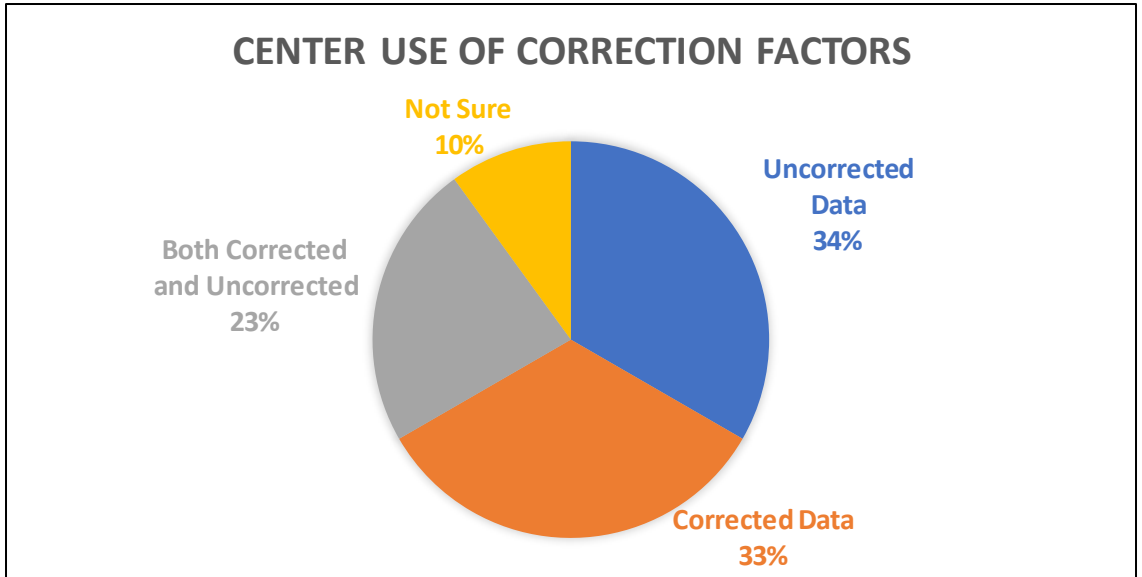
- Original Survey (Feb 2023)
  - 36 ADRC responses
    - Specimen types collected
    - Biomarker analysis at various labs
    - Most centers already sharing data
    - Barriers to submitting data to NACC
      - Need clear guidelines on variables to be uploaded to NACC
      - The process needs to be refined to allow quality, harmonized data that would be used by investigators

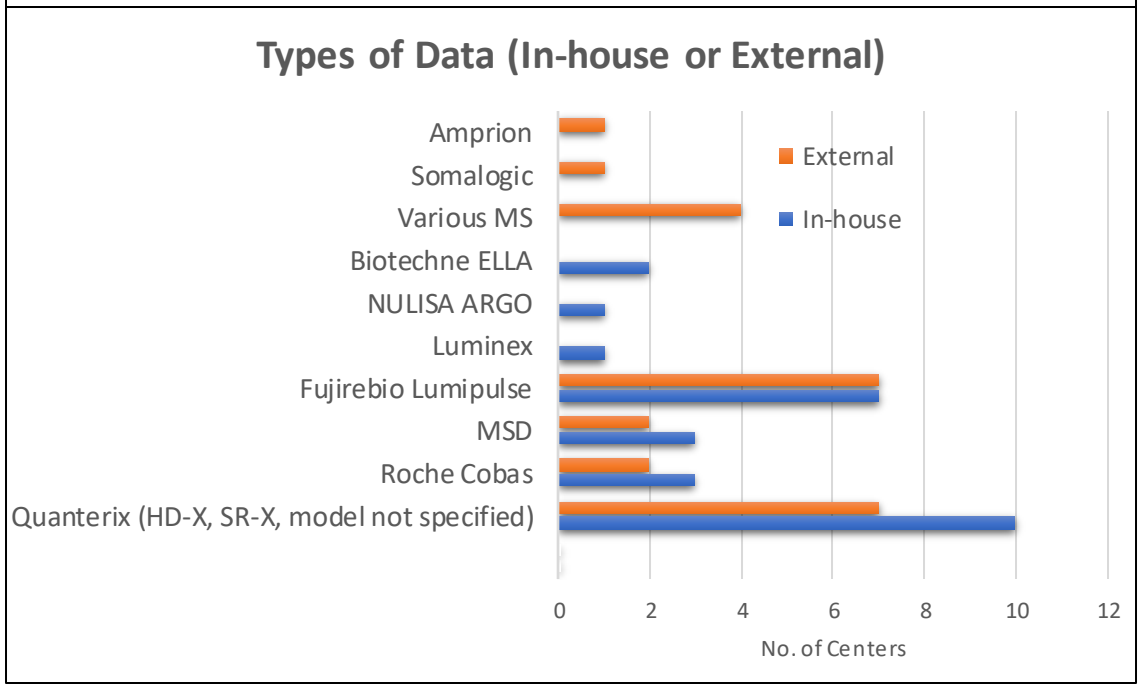




ADRC Surveys

- Recent Survey (Apr 2024)
  - 31 ADRC responses
    - 29/31 ADRCs interested in uploading blood and/or CSF data to NACC
      - Historical data as far back as 1/1/2000
    - Variety of in-house and external assay platforms/types utilized
    - Mix of corrected and uncorrected data to be returned
    - Most centers will have data core or lab staff submit the data





ADRC Surveys

- Major Takeaways
  - Centers have a lot of data to share!
  - Process must be streamlined with clear instructions
  - Variables must allow for many platforms/data types/data correction factors
  - Variables must capture enough info to allow investigators to make decisions on combining data and downstream analyses

Workgroup Recommended Variables

Minimum Variables

Site/Specimen

- ADRC site
- Participant ID
- Sample collection date
- Collection time
- Collection tube type
- Time to freeze
- Analyzed specimen type

Lab/Assay

- Assay platform
- Instrument model
- Assay Manufacturer
- Assay catalog number
- Assay lot number
- Lab name
- Instrument ID
- Batch ID
- Analysis date

Data/Analysis

- Biomarker
- Biomarker Concentration (dilution corrected)
- Biomarker concentration unit
- Were controls run (Y/N)
- Was data corrected for lot, batch, and/or instrument differences (Y/N)

Desired Variables

Site/Specimen

- Fasting collection (Y/N)
- Specimen Freeze/Thaw
- Time to centrifugation
- Centrifugation speed
- Centrifugation temperature
- If CSF: Bloody LP (Y/N)
- Protocol Deviation (Y/N)

Data/Analysis

- Type of controls utilized: (Manufacturer provided; in house pooled controls; both)

Variables-If available

- Fasting duration
- Needle type
- Needle gauge
- Storage tube type
- Position of patient during collection (sitting; standing; lying down)
- Temp between collection and centrifugation

<u>Blood</u>

- Tourniquet (Y/N)
- Hemolysis (Y/N)

<u>CSF</u>

- Blood also collected (Y/N)
- Routine assays run (RBC, WBC, etc)

Next Steps

- Work with Biomarker Steering Committee to finalize variables
- Work with NACC to fine tune and implement incorporation of variables

Thank you!

Workgroup Members

- Minerva Carrasquillo
- Kaitlin Casaletto
- Kelley Faber
- Mingzaho Hu
- Hesam Jahanian
- Nick Kanaan
- Tommy Karikari
- Argentina Lario Lago
- Jill Morris
- Angus Nairn
- Matthew Perkins
- Jagan Pillai
- Jonathan Reader
- Tom Register
- Clairisa Stayton
- Tim Van Meter
- Ted Wilson
- Lynn Bekris
- Ricardo Osorio

NIA Representatives

- Cerise Elliot
- Nina Silverberg

NACC Representatives

- Sarah Biber
- Hannah Rosentreter
- Kathryn Gauthreaux
- Jess Welsch
- Heather O'Connell

Special thank you to the Biomarker Core Steering Committee for input and guidance throughout the process!