



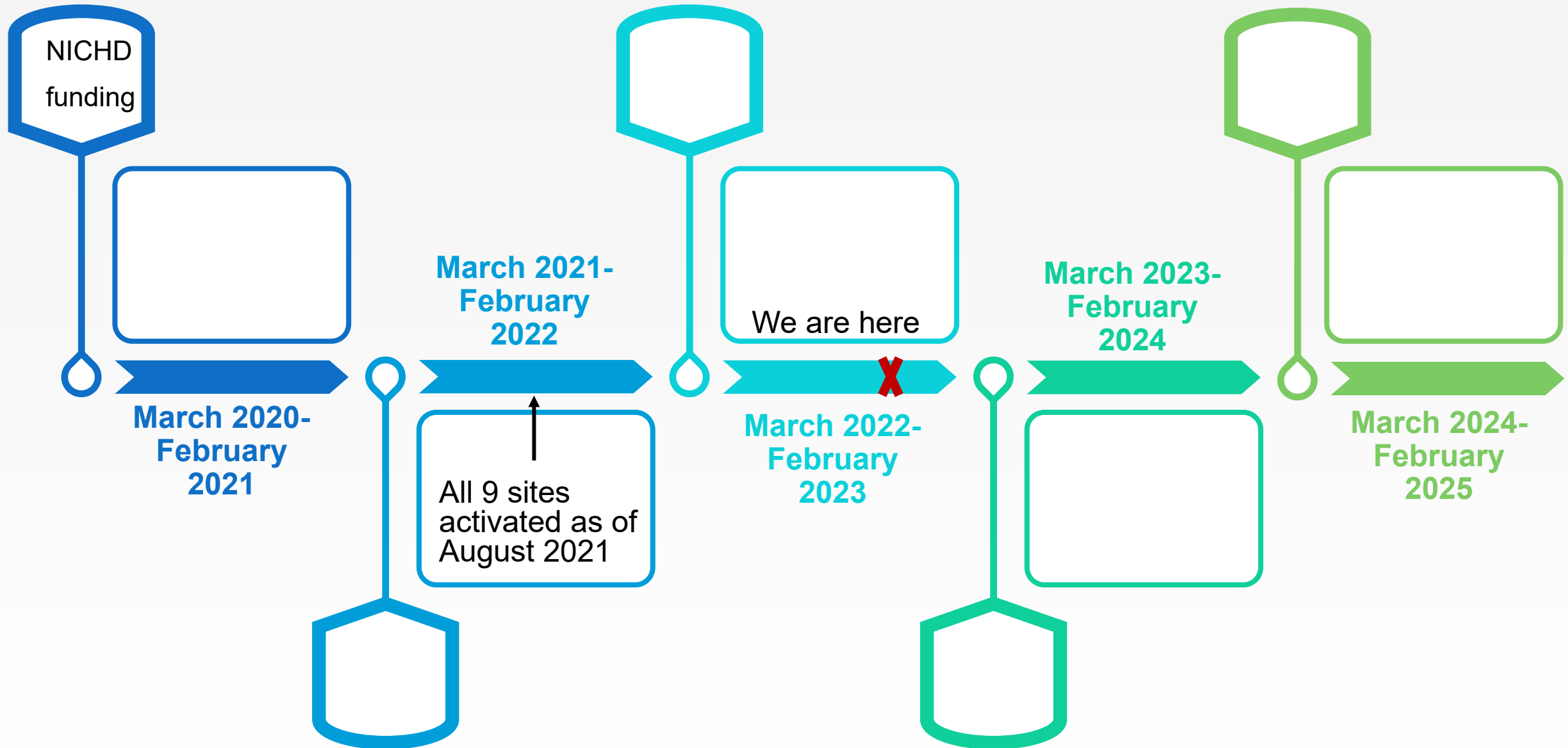
# RAFT Monthly All-Sites

November 21, 2022, 10-11 am EST

# Agenda

- Enrollment report
  - Screen fail review
- NAFTNet follow-up
  - Abstract/manuscript update, DSMB
- Research ethics consult
  - Tuesday December 6<sup>th</sup>, 2-3:30 pm Eastern
- Ongoing recruitment

# RAFT Trial Timeline



# RAFT Prescreen, Screen & Enrollment Report

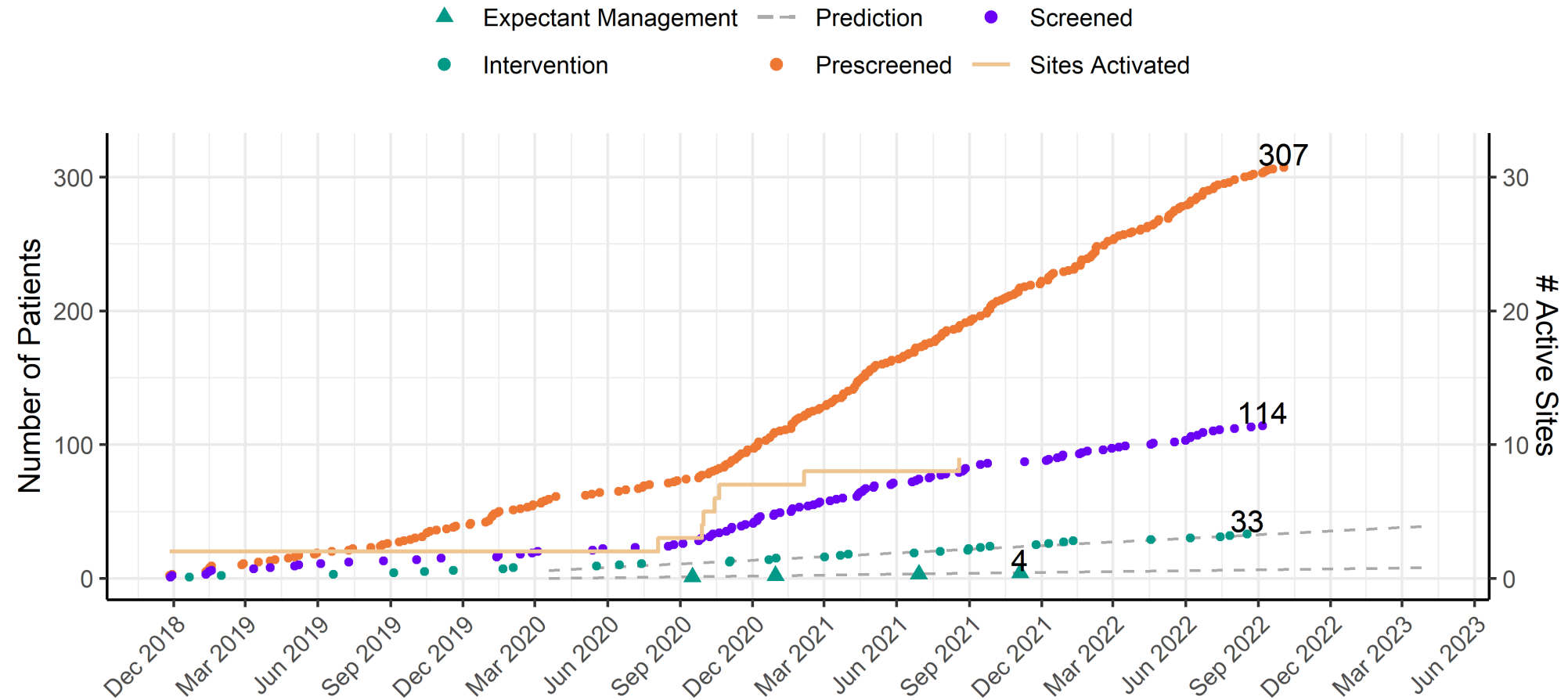
Data is as of November 14, 2022

Numbers in parentheses indicate changes since last report date October 10, 2022

Site Name	Pre-Screened	Screened	Enrolled	FRF [I/EM]	CoBRA [I/EM]	Last Pre-Screened	Last Screened	Last Enrolled
000 - Johns Hopkins University	108	35	11	5 [5/0]	6 [5/1]	2022-09-06	2022-09-06	2022-08-18
067 - Stanford University	29	14	7	1 [1/0]	6 [6/0]	2022-05-13	2021-08-02	2021-08-31
096 - University of Southern California	3	2	0	0 [0/0]	0 [0/0]	2021-09-28	2021-01-19	
282 - Children's Hospital of Philadelphia	40	7	7	4 [3/1]	3 [1/2]	2022-07-08	2022-06-23	2022-07-27
283 - Mayo Clinic	5	5	4	2 [2/0]	2 [2/0]	2022-06-23	2022-06-23	2022-07-15
284 - University of California San Francisco	12	3	1	1 [1/0]	0 [0/0]	2022-10-03	2021-06-25	2021-07-26
285 - Columbia University	47	21	0	0 [0/0]	0 [0/0]	2022-06-24	2022-06-08	
286 - University of Colorado	10	2	2	0 [0/0]	2 [2/0]	2022-06-06	2021-12-28	2021-12-29
462 - University of Texas Houston	53	25	5	1 [1/0]	4 [4/0]	2022-09-12	2022-08-23	2022-01-10
<b>Total</b>	<b>307</b>	<b>114</b>	<b>37</b>	<b>14 [13/1]</b>	<b>23 [20/3]</b>	<b>2022-10-03</b>	<b>2022-09-06</b>	<b>2022-08-18</b>

\* USC enrolled one participant, who is transferred to Stanford.

# RAFT Prescreen, Screening and Enrollment Over Time



# Demographics

		Screened		Enrolled	
		Count	%	Count	%
Total	Total	114		37	
Race	[Blank]	10	8.8%	0	0.0%
	American Indian or Alaska Native	1	0.9%	0	0.0%
	Asian	2	1.8%	0	0.0%
	Black or African American	15	13.2%	1	2.7%
	Native Hawaiian or Other Pacific Islander	2	1.8%	1	2.7%
	Other	1	0.9%	1	2.7%
	Unknown	2	1.8%	0	0.0%
	White	81	71.1%	34	91.9%
Ethnicity	[Blank]	4	3.5%	0	0.0%
	Hispanic or Latino	30	26.3%	7	18.9%
	Not Hispanic or Latino	80	70.2%	30	81.1%
Education	[Blank]	4	3.5%	1	2.7%
	Associates	11	9.6%	5	13.5%
	Bachelors	21	18.4%	10	27.0%
	High School/GED	14	12.3%	7	18.9%
	Master's	6	5.3%	4	10.8%
	Unknown	58	50.9%	10	27.0%

# Pre-Screen Failure Primary Reasons

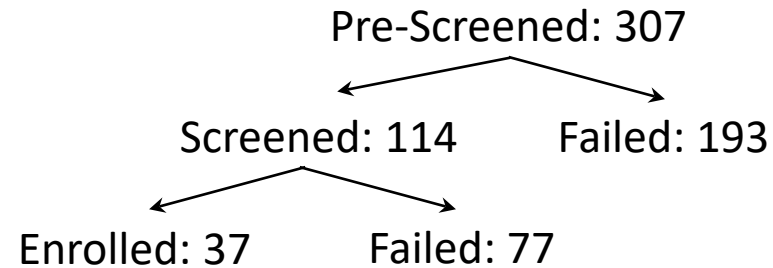
Pre-Screen Failure Reason	Count
[Blank]	3
Amniotic fluid present after 22 weeks	25
Evidence of abruption placentae	1
Maternal age < 18 years	3
Maternal depression	2
Multiple congenital anomalies of the fetus	23
Multiple gestation	11
Other	28
Participant declined participation	8
PPROM	13
Pursuing termination	20
Referral came too close to 26w GA to complete screening	7
Referred to another RAFT site	10
Significant maternal co-morbid factors	7
Suspect genetic abnormality	3
Unable to get insurance authorization	18
Unable to recruit due to COVID-19	4
Unable to travel or unwilling to relocate	14

# Pre-Screening Failure Reason = 'Other'

Site	patient_id	reason_type	fail_reason	fail_reason_spec
000 - Johns Hopkins University	3996-11	Primary	Other	Declined diagnostic amnioinfusion and genetic testing.
000 - Johns Hopkins University	3996-12	Primary	Other	Multiple congenital anomalies
000 - Johns Hopkins University	3996-20	Primary	Other	Declined procedures
000 - Johns Hopkins University	3996-27	Primary	Other	No show on 10/23/2019
000 - Johns Hopkins University	3996-29	Primary	Other	In-utero fetal demise noted at time of screening
000 - Johns Hopkins University	3996-46	Primary	Other	Not interested in study
000 - Johns Hopkins University	3996-5	Primary	Other	25w2d on 1/16/2019. No genetic testing
000 - Johns Hopkins University	3996-60	Primary	Other	undecided
000 - Johns Hopkins University	3996-63	Primary	Other	Positive for CMV
000 - Johns Hopkins University	3996-7	Primary	Other	WV Medicaid
000 - Johns Hopkins University	3996-72	Primary	Other	Fetus presents with small kidneys and oligohydramnios
000 - Johns Hopkins University	3996-95	Primary	Other	BRA arm on hold
067 - Stanford University	3761-18	Primary	Other	Medical records not sent to Stanford
067 - Stanford University	3761-21	Primary	Other	Patient did not respond to communications
096 - University of Southern California	4092-5	Primary	Other	SGA; Abnormal dopplers; Placental insufficiency
282 - Children's Hospital of Philadelphia	4093-21	Secondary	Other	Maternal psychosocial concerns
282 - Children's Hospital of Philadelphia	4093-34	Secondary	Other	Religious/Spiritual Beliefs
284 - University of California San Francisco	4095-12	Primary	Other	did not meet eligibility requirements
284 - University of California San Francisco	4095-7	Primary	Other	Declined diagnostic testing
285 - Columbia University	4091-3	Primary	Other	echogenic kidneys and cyst dysplasia
285 - Columbia University	4091-31	Primary	Other	LUTO
285 - Columbia University	4091-37	Primary	Other	No documented agenesis or renal failure
285 - Columbia University	4091-38	Primary	Other	Trisomy 21
285 - Columbia University	4091-39	Primary	Other	Fetus not seen
285 - Columbia University	4091-4	Primary	Other	absent L kidney, multicystic R kidney
286 - University of Colorado	4090-10	Primary	Other	AFI too high to meet inclusion criteria
286 - University of Colorado	4090-5	Primary	Other	active bleeding and clots above cervix
462 - University of Texas Houston	5127-22	Primary	Other	No maternal coverage with insurance
462 - University of Texas Houston	5127-31	Primary	Other	Fetus with other anomalies
462 - University of Texas Houston	5127-4	Primary	Other	Pt declined to come to Texas
462 - University of Texas Houston	5127-53	Primary	Other	Pt desired amnioinfusions for compassionate care



# Screen Failure



Total Failures	77
<b>Inclusion</b>	
Anhydramnios before 22 weeks	12
Amniofusion can occur before 26 weeks	40
No termination of pregnancy	14
18 or older	0
Willing to deliver at RAFT Center	15
Willing for postnatal care at RAFT Center	15
Completed consults	41

## Exclusion

Cervix < 2.5cm	1
No pathogenic findings	9
Other congenital anomalies	20
Chorioamnionitis	1
Abruption placentae	2
Membrane rupture	5
Choriamniotic separation	3
Preterm labor	1
Multiple gestation	0
Severe medical condition in pregnancy	4
Depression score > 17	1
Maternal body habitus	0
Placental location	0
Other technical limitations	0

# Protocol Deviations and Adverse Events

Site	Enrolled	Adverse Event	Serious Adverse Event	Protocol Deviation
000 - Johns Hopkins University Pilot	6	12	2	61
000 - Johns Hopkins University	11	8	0	4
067 - Stanford University	7	17	3	11
282 - Children's Hospital of Philadelphia	7	15	0	9
283 - Mayo Clinic	4	5	1	3
284 - University of California San Francisco	1	3	0	0
286 - University of Colorado	2	3	1	2
462 - University of Texas Houston	5	6	1	6

# Queries

Site	Open Queries	Average Query Life (days)	Longest Open Query (days)	Closed Queries	Average Resolution Days
000 - Johns Hopkins University	7	43.5	111.8	341	47.3
067 - Stanford University	13	104.8	671.9	332	119.4
282 - Children's Hospital of Philadelphia	6	25.3	51.9	96	48.9
283 - Mayo Clinic	12	103.9	259	104	39.9
284 - University of California San Francisco	3	119.2	226.6	65	131.6
286 - University of Colorado	7	85	153.8	22	86.3
462 - University of Texas Houston	3	128.6	153.9	169	44.5
<b>Overall</b>	<b>51</b>	<b>86.3</b>	<b>671.9</b>	<b>1129</b>	<b>73.1</b>

# NAFTNet

- Submit late-breaking abstract with 20 BRA participant data for SMFM meeting 2023
  - Submitted 11/7, decision expected by 11/27
- Draft manuscript – goal for draft by end of December
- Post-natal management guideline priorities defined
- Next DSMB meeting is Friday 12/9 – will provide updated survival/outcome data and progress to date

## CLINICAL RESEARCH ETHICS CONSULTATION COLLABORATIVE

- Presentation of key facts and questions to consult service (10-15 min)
- Consultative group asks questions (30-40 min)
- Feedback from consultants

# Questions?

- *What should we disclose to potential participants regarding interim results/observations?*
  - *Revised consent and publishing BRA experience*
- How do we move forward in clinical practice in the face of the DSMB-guided decision to stop enrolling in the BRA arm of the trial?
  - Potential participants who are asking for the prenatal intervention now do not have access through the trial structure, and if obtaining at other centers we do not have access to that data

# Questions?