

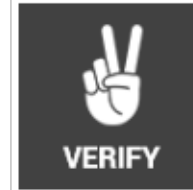


# NDMC Updates

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StrokeNet National Data Management Center

Medical University of South Carolina



375,000  
CRFs!

50,000  
queries!

1%  
error  
rate

## List: Summary by Project

#	Project name	CRFs posted	CRFs data entered	CRFs submitted	% Site CRFs first submitted by due date	Site CRF data entry over due	DCRs	Average DCR response days	DCRs closed	Average DCR closing days	DCRs not responded	DCRs responded not closed	Open rule violation	Confirmed warning rule violation	Confirmed protocol violation	% Site data error	Updated on
	<b>Total</b>	<b>425020</b>	<b>376135</b>	<b>375692</b>		<b>405</b>	<b>50061</b>		<b>48306</b>		<b>621</b>	<b>1134</b>	<b>580</b>	<b>11773</b>	<b>743</b>		
1	TeleRehab	7598	6702	6702	80.2		298	9.5	298	24.6			0	10	136	0.27	17-Sep-2024
2	DEFUSE3	6659	5474	5469	85.1		1124	6.1	1114	16.6		10	5	266	21	0.91	17-Sep-2024
3	ARCADIA	121028	111037	110958	78.1	33	11984	27.1	11737	103.4	79	168	114	1656	31	0.5	17-Sep-2024
4	MOST	13188	10584	10583	81.6		4007	16.7	3992	57	8	7	0	236	146	0.92	17-Sep-2024
5	TRANSPORT2	14870	13161	13161	70.8		1060	18	1059	62.4	1		0	46	4	0.31	17-Sep-2024
6	SleepSMART	110927	100479	100415	81.9	104	12567	16.3	12302	69.4	165	100	44	1711	231	0.54	17-Sep-2024
7	ASPIRE	22386	18800	18742	80.3	52	2514	10.8	2468	24	32	14	53	537	7	0.55	17-Sep-2024
8	SATURN	49057	44997	44967	74.7	18	6430	14.8	6122	40.6	76	232	22	3066	41	1.52	17-Sep-2024
9	I-ACQUIRE	28286	23775	23759	58.4	74	1009	33.6	974	59.9	29	6	49	1024	3	0.11	17-Sep-2024
10	ARCADIA-CSI	3432	3323	3323	71.3	1	896	33.9	894	84.3	1	1	0	3	3	3.86	17-Sep-2024
11	FASTEST	15574	12889	12847	77.2	42	3540	12.1	3122	28.6	121	297	64	854	37	0.66	17-Sep-2024
12	VERIFY	7127	6205	6200	83.8	8	798	7.5	765	22.4	24	9	17	148	29	0.34	17-Sep-2024
13	CAPTIVA	24291	18237	18099	80.8	66	3781	9.4	3424	35.4	73	284	178	2129	54	0.57	17-Sep-2024
14	FOCAS	374	283	280	80.6	7	28	4.1	15	7.8	10	3	30	8	0	0.1	17-Sep-2024
15	SISTER	223	189	187	83.2		25	4.1	20	6.5	2	3	4	79	0	0.13	17-Sep-2024

Note: Data in this report are updated daily. Subjects enrolled within 24 hours may not be included.

CRFs posted: all required CRFs plus data entered optional CRFs, includes CRFs with data provided by sites and other parties.

% Site CRFs first submitted by due date: includes CRFs with data provided by sites only.

Site CRF data entry over due: includes CRFs with data provided by sites only.

% Site data error: includes CRFs with data provided by sites only.

# Completed



## CRF Data Entry Summary by Project

Project name	CRFs posted	CRFs submitted	% Site CRFs first submitted by due date	DCRs	Average DCR response days	DCRs closed	Average DCR closing days	Confirmed protocol violation	% Site data error
TeleRehab	7598	6702	80.2	298	9.5	298	24.6	136	0.27
DEFUSE3	6659	5469	85.1	1124	6.1	1114	16.6	21	0.91
ARCADIA	121028	110958	78.1	11984	27.1	11737	103.4	31	0.5
MOST	13188	10583	81.6	4007	16.7	3992	57	146	0.92
ARCADIA-CSI	3432	3323	71.3	896	33.9	894	84.3	3	3.86

# List: Subject Demographics Summary by Project

Help

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Page Actions

#	Project name	Sample size	Enrolling sites	Subjects enrolled	Last enrollment date	% Female	% Male	% Hispanic	% Not-Hispanic	% American Indian / Alaska Native	% Asian	% Black / African American ▲	% Native Hawaiian or Pacific Islander	% White	% More than one race	Updated on
	<b>Total</b>	<b>12367</b>	<b>807</b>	<b>5987</b>	<b>9/17/2024</b>	<b>45.6</b>	<b>54.4</b>	<b>9.7</b>	<b>89.8</b>	<b>0.5</b>	<b>8</b>	<b>22.6</b>	<b>0.4</b>	<b>66.2</b>	<b>0.6</b>	
1	CAPTIVA-MRI	300	2	3	04-Sep-2024	66.7	33.3		100		33.3			66.7		17-Sep-2024
2	SISTER	300	6	7	05-Sep-2024	28.6	71.4		100	14.3				85.7		17-Sep-2024
3	DEFUSE3	476	38	182	23-May-2017	50.5	49.5	13.2	86.3	0.5	3.3	8.2		86.8		17-Sep-2024
4	FASTEST	860	71	532	17-Sep-2024	35	65	8.6	91	0.2	55.1	8.3	0.4	33.8		17-Sep-2024
5	I-ACQUIRE	240	16	213	16-Sep-2024	48.4	51.6	17.8	80.3		3.8	8.5	0.5	78.9	2.8	17-Sep-2024
6	SATURN	1456	103	594	13-Sep-2024	55.6	44.4	10.4	89.4	0.5	4.5	9.6	0.2	84.8	0.2	17-Sep-2024
7	ASPIRE	700	106	334	10-Sep-2024	44.9	55.1	6.6	91.9	0.3	5.4	14.1	0.9	75.7	0.9	17-Sep-2024
8	ARCADIA	1100	141	1015	14-Dec-2022	54.3	45.7	8.1	91.4	0.4	1.7	21.1	0.3	74.9	0.3	17-Sep-2024
9	FOCAS	80	7	8	10-Sep-2024	12.5	87.5	25	75		25	25		37.5		17-Sep-2024
10	MOST	1200	57	514	01-Jul-2023	49.8	50.2	7.8	91.8		2.7	25.1	0.2	71.4	0.2	17-Sep-2024
11	TeleRehab	124	11	124	03-Jan-2018	27.4	72.6	2.4	96		8.1	26.6		64.5		17-Sep-2024
12	SleepSMART	3062	117	1593	13-Sep-2024	42.1	57.9	10.2	89.4	0.8	3.3	28.6	0.4	64.3	0.5	17-Sep-2024
13	VERIFY	657	23	241	08-Sep-2024	38.2	61.8	7.5	91.3		1.2	38.2	0.4	58.1	0.8	17-Sep-2024
14	CAPTIVA	1683	95	498	16-Sep-2024	42	58	14.1	85.7	1.2	4	38.8	1	49.6	1.6	17-Sep-2024
15	TRANSPORT2	129	14	129	14-Jun-2024	41.9	58.1	8.5	91.5		3.1	41.1		53.5	0.8	17-Sep-2024

Note 1. Only subjects counting towards the sample size are included.  
 2. Subjects enrolled in ancillary studies are not counted separately, because they have been counted in their parent projects.  
 3. Percentages in the Total row are obtained by the total subject counts in the demographic category divided by total subjects enrolled across all projects.  
 4. Data in this report are updated daily. Subjects enrolled within 24 hours may be not included.



6,000 patients

## List: Subject Demographics Summary by Project

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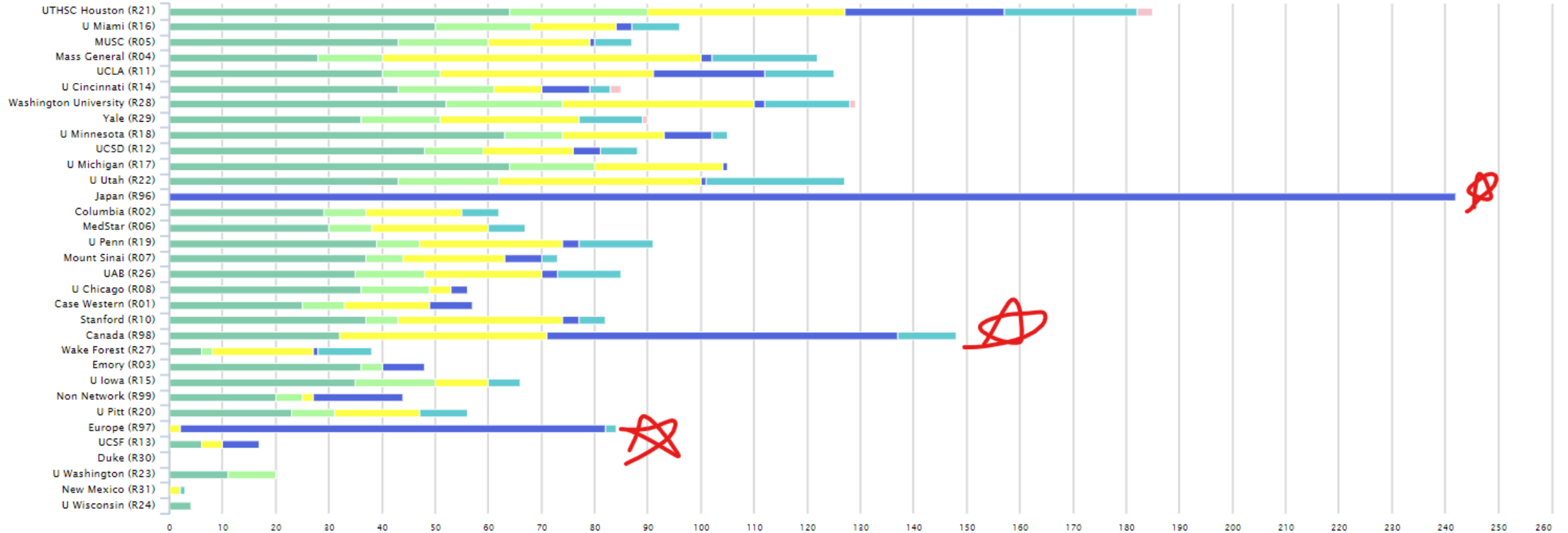
#	Project name	Sample size	Enrolling sites	Subjects enrolled	Last enrollment date	% Female	% Male	% Hispanic	% Not-Hispanic	% American Indian / Alaska Native	% Asian	% Black / African American	% Native Hawaiian or Pacific Islander	% White
	<b>Total</b>	<b>12367</b>	<b>810</b>	<b>6006</b>	<b>9/22/2024</b>	<b>45.6</b>	<b>54.4</b>	<b>9.7</b>	<b>89.7</b>	<b>0.5</b>	<b>8</b>	<b>22.6</b>	<b>0.4</b>	<b>66.1</b>
1	FASTEST	860	72	536	22-Sep-2024	35.1	64.9	8.8	90.9	0.2	55	8.4	0.4	33.6
2	FOCAS	80	7	8	10-Sep-2024	12.5	87.5	25	75		25	25		37.5
3	CAPTIVA	1683	96	502	18-Sep-2024	41.8	58.2	14.3	85.5	1.2	4	38.8	1	49.6
4	TRANSPORT2	129	14	129	14-Jun-2024	41.9	58.1	8.5	91.5		3.1	41.1		53.5
5	VERIFY	657	23	243	08-Sep-2024	38.7	61.3	7.4	91.4		1.2	37.9	0.4	58.4
6	SleepSMART	3062	117	1595	18-Sep-2024	42	58	10.2	89.4	0.8	3.3	28.7	0.4	64.3
7	TeleRehab	124	11	124	03-Jan-2018	27.4	72.6	2.4	96		8.1	26.6		64.5
8	CAPTIVA-MRI	300	2	3	04-Sep-2024	66.7	33.3		100		33.3			66.7
9	MOST	1200	57	514	01-Jul-2023	49.8	50.2	7.8	91.8		2.7	25.1	0.2	71.4
10	ARCADIA	1100	141	1015	14-Dec-2022	54.3	45.7	8.1	91.4	0.4	1.7	21.1	0.3	74.9
11	ASPIRE	700	107	336	19-Sep-2024	44.9	55.1	6.5	92	0.3	5.7	14	0.9	75.6
12	I-ACQUIRE	240	16	214	20-Sep-2024	48.1	51.9	18.2	79.9		3.7	8.4	0.5	78.5
13	SATURN	1456	103	598	20-Sep-2024	55.7	44.3	10.4	89.5	0.5	4.5	9.5	0.2	84.9
14	SISTER	300	6	7	05-Sep-2024	28.6	71.4		100	14.3				85.7
15	DEFUSE3	476	38	182	23-May-2017	50.5	49.5	13.2	86.3	0.5	3.3	8.2		86.8

Note 1. Only subjects counting towards the sample size are included.  
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 4. Data in this report are updated daily. Subjects enrolled within 24 hours may be not included.

# Increased International Trials: Subject Enrollment

A. Subject Enrollment by RCC (9/30/2013 - 09/17/2024)

Time window: 30 Sep 2013 Through 17 Sep 2024 Refresh



Total number of subjects enrolled from 9/30/2013 to 09/17/2024 in StrokeNet sites grouped by RCC.

TeleRehab DEFUSE3 ARCADIA SleepSMART TRANSPORT2 I-ACQUIRE MOST ARCADIA-CSI ASPIRE SATURN FASTEST SATURN-MRI VERIFY CAPTIVA FOCAS SISTER CAPTIVA-MRI

# WebDCU upgrade to .NET platform

- 2-factor user authentication
- Increased data security protection
- More robust tools for data validation logic rules and skip pattern set up
- Future StrokeNet studies -- new platform upon development
- Ongoing StrokeNet studies - upgraded platform over the coming year(s)



# Standardization to increase efficiency

- CRFs -- library form structure, includes data field definitions, code, data validation rules, skip patterns, and associated emails
- Enhance the system stability, increase new project development efficiency and facilitate cross-project summary report generation.
- Integration of procedures at clinical sites, central pharmacy, central lab, and safety and efficacy outcome adjudication team members

# STEP



FDA approval

cIRB approval

CTA and cIRB  
packets sent

Site onboarding

DSMB meeting

Protocol training

First site  
released

June 2023

May 2024

June 2024

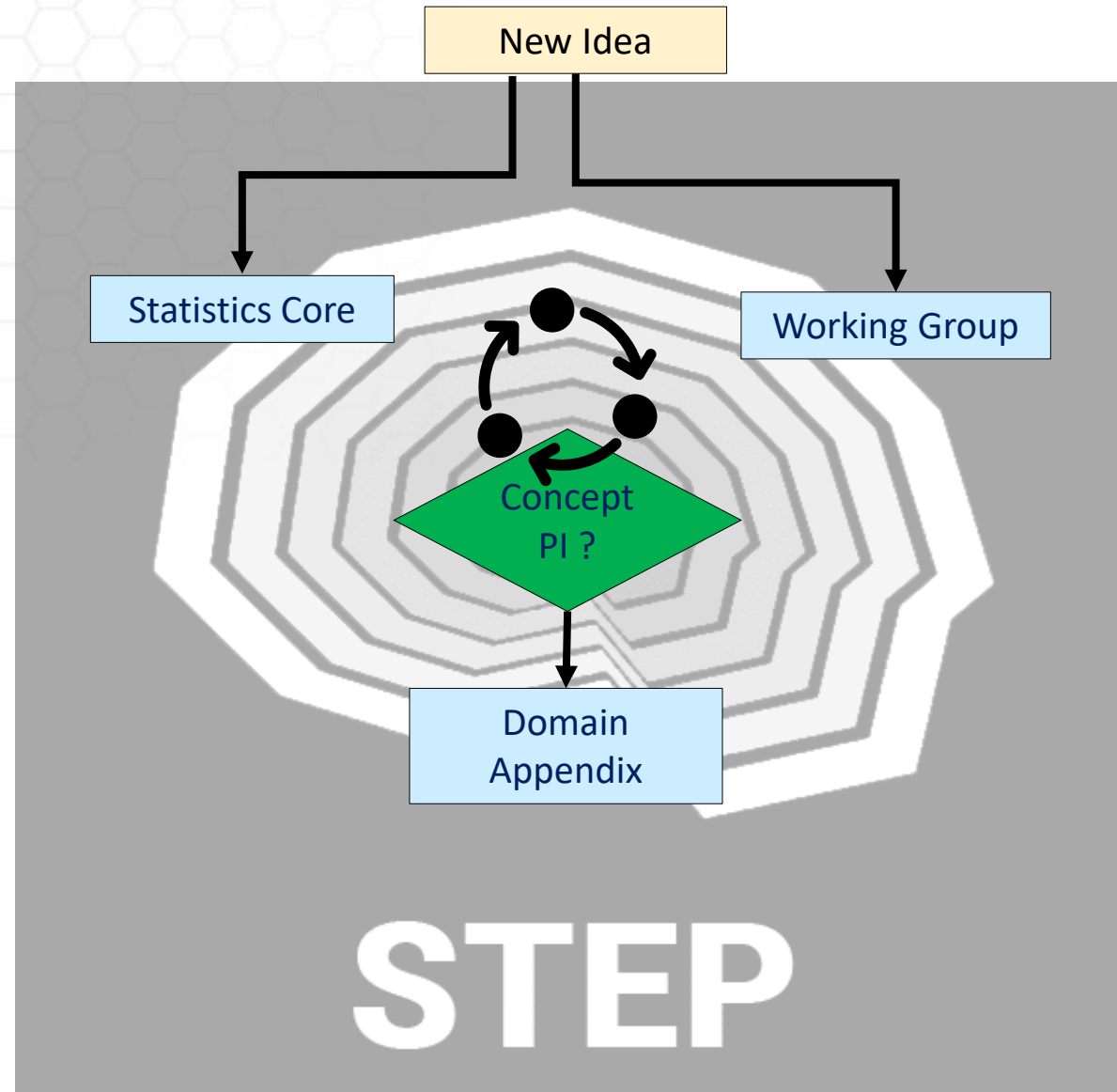
August 2024

Sept 2024

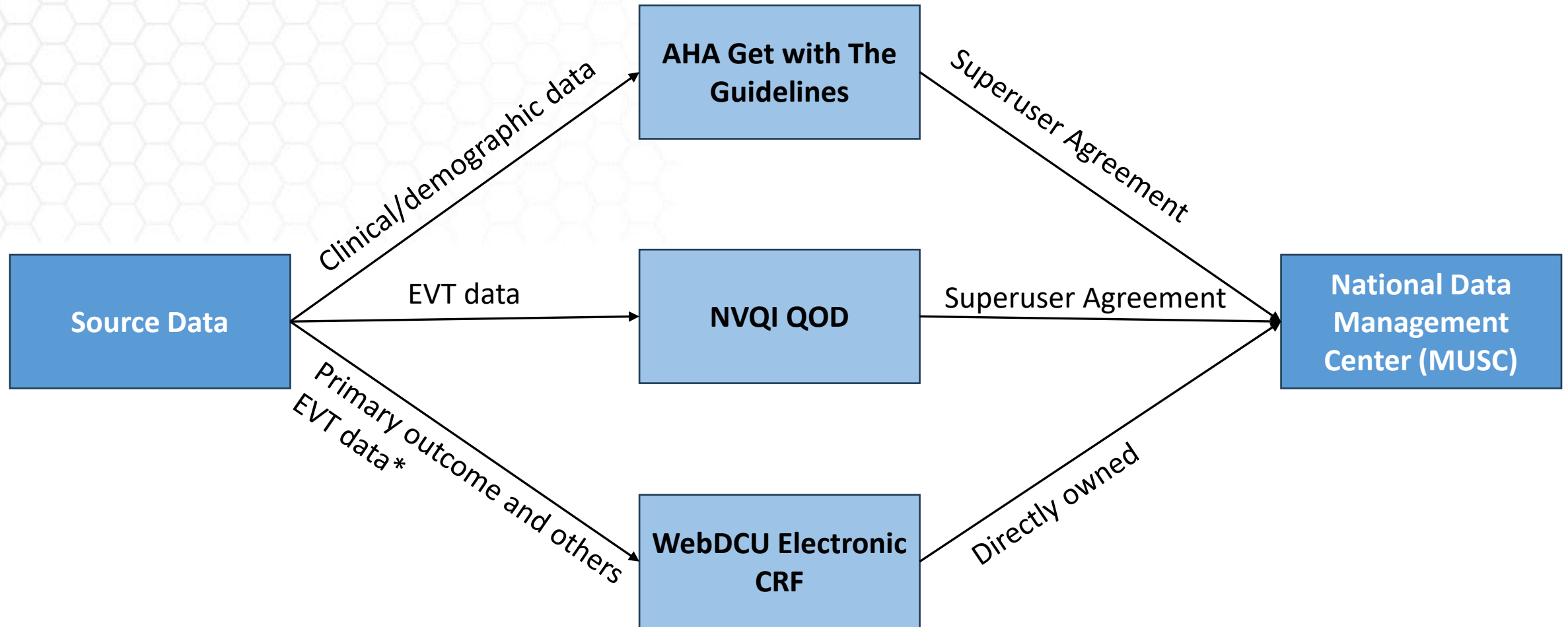
October 2024

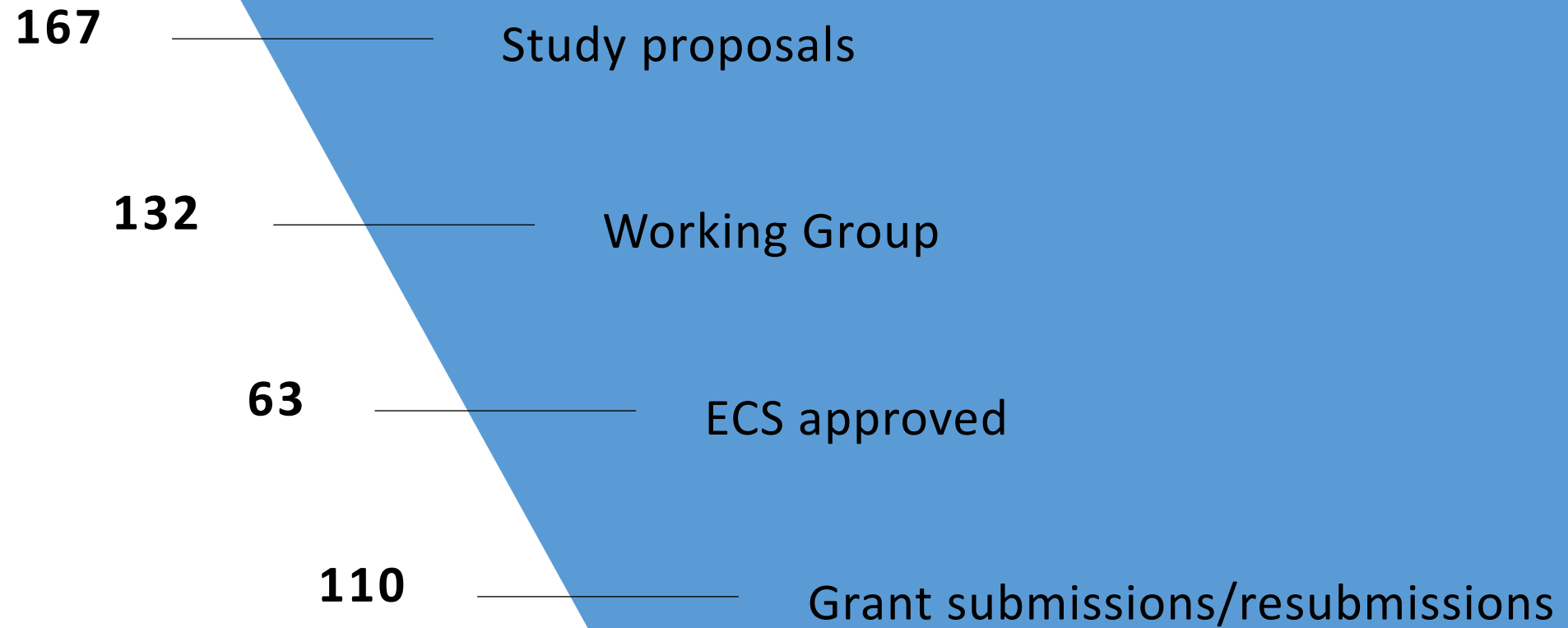
Nov 2024

# New Concept Development Work-Flow



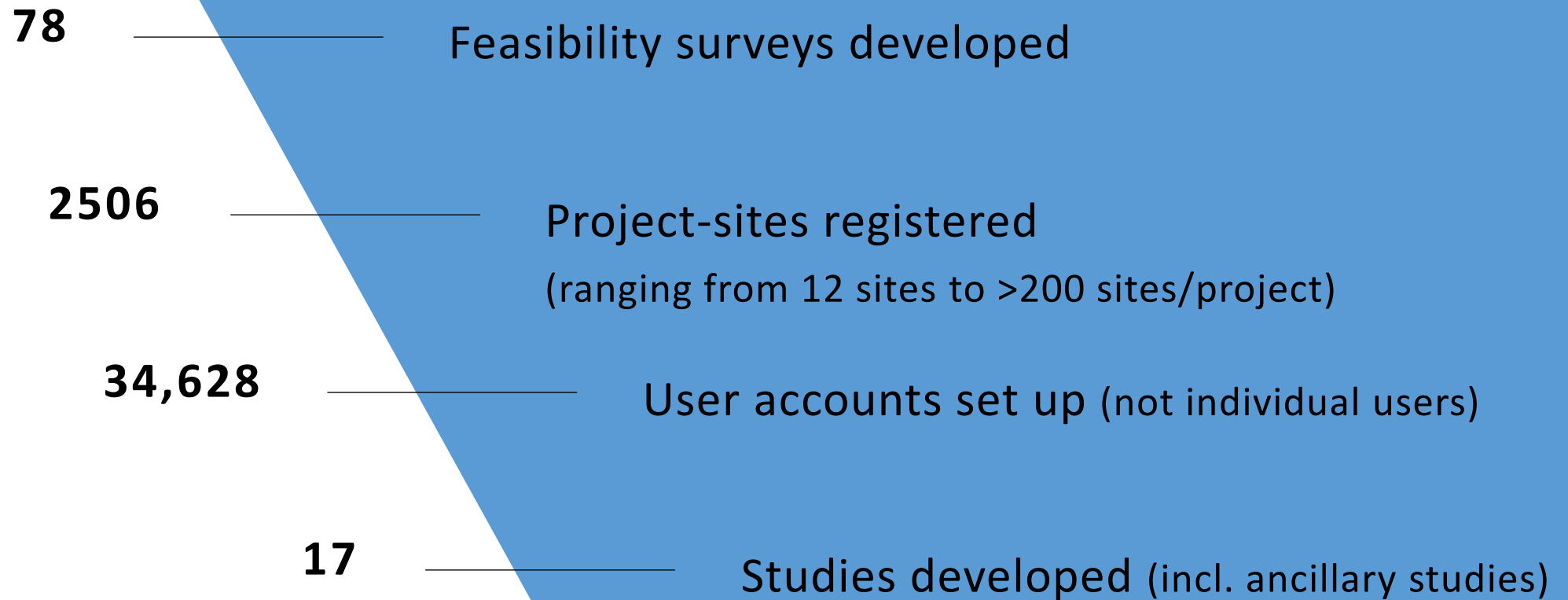
# STEP Data Transfer Procedures



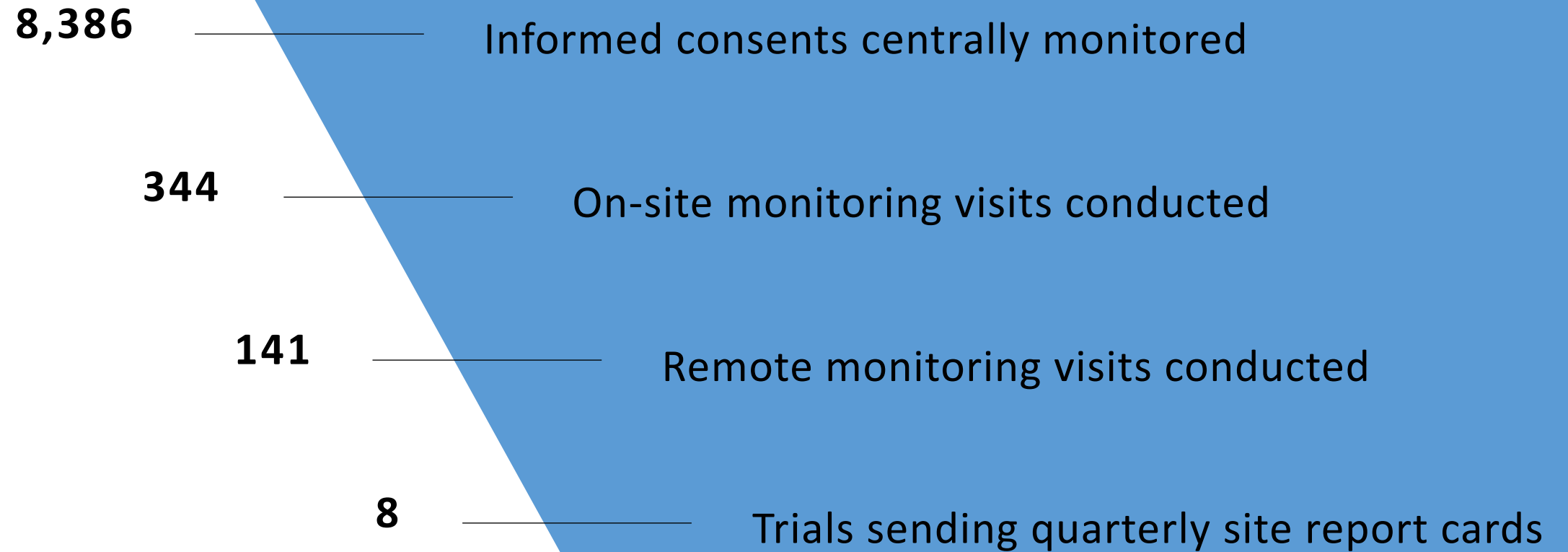


**BIOSTATISTICS**





## PROJECT MANAGEMENT



## SITE MONITORING