

**PARITY Newsletter** 

March 2021 • Edition 32

### PLEASE READ THIS ENTIRE NEWSLETTER FOR IMPORTANT INFORMATION AND DEADLINES AND TO LEARN ABOUT EXCITING STUDY UPDATES!

Dear friends and colleagues:

We would like to thank you for your continued dedication to the PARITY trial. At this time, we would also like to provide you with an update on data collection and validation, event adjudication and next steps for the study!

#### Data Collection and Validation

At present, we are missing final follow-up data for only *six* PARITY participants! We are now in the process of validating the data from Level 2 to Level 3, which involves a very intense final review of the data with advanced statistical software by our study statistician. This is why you may notice new queries on a previously 'clean' study participant. As we move through the final stages of data validation, we truly appreciate your diligence in responding to queries to ensure the highest quality data. We have already validated 41% of participants up to Level 3. We intend to lock the database no later than **Friday, April 30**. Please see **Page 2** for further details.

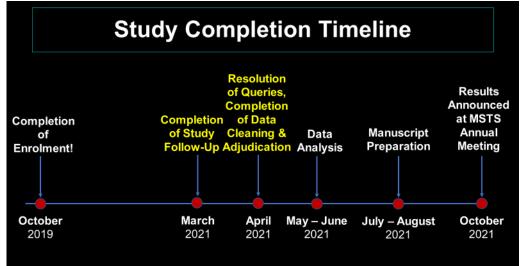
#### Adjudication

At present, we have adjudicated 85% of all required study events and anticipate completing event adjudication by the end of April 2021. Please see **Page 2** for further details.

# IN <u>OCTOBER 2021</u> (ONLY 6 SHORT MONTHS AWAY), WE PLAN TO PUBLISH THE PARITY TRIAL IN A TOP 5 JOURNAL AND SIMULTANEOUSLY PRESENT RESULTS AT THE MSTS 2021 ANNUAL MEETING!

#### Next Steps

We have only a few months left before study close-out! We expect data analysis to begin in early May 2021. Once data analysis occurs, we intend to finalize and submit the manuscript to a top 5 journal for an expedited review in order to simultaneously publish and present the study results at the Musculoskeletal Tumor Society (MSTS) Annual Meeting this fall. Until then, please ensure your ethics approval remains up-todate and open until the **Methods Centre** notifies you otherwise, and all annual ethics approvals are sent to the **Methods Centre**.





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## PARITY Data Collection, Cleaning and Validation

PARITY data will proceed through 4 levels of data validation, with the final level being Site Investigator sign-off. These various levels of data validation will ensure results will be of the highest possible quality. We have set a deadline of **Friday**, **April 9** for the complete resolution of all data queries by sites in order to give the Methods Centre time to address any remaining issues prior to the deadline to lock the database by Friday, April 30. Victoria will continue to notify you of any new queries that arise as we progress through the stages of data validation. You may also check ongoing queries in the iDataFax database. We also require the final follow-up data for the **six** outstanding participants to be entered into the database no later than **Wednesday**, **March 10** in order to give the Methods Centre time to address any queries and validate the data by the deadline of Friday, April 9.

**The below table** highlights sites with outstanding queries for all screened participants. If your site has not yet been reviewed at Level 3 (marked as TBD), please be aware that new queries on enrolled participants may arise once the Level 3 validation process occurs.

### Why Are There New Queries on Previously Clean Participants?

As we move to higher levels of data validation, new queries may be placed on previously 'clean' participants, as the cleaning procedures are more robust and to help better categorize adverse events and 'other' categories. Please review your site's participant data in iDataFax for **ALL PARTICIPANTS** regularly to ensure that you have adequately responded to any new queries.

## **PARITY Adjudication**

Event adjudication continues for the trial. **The below table** highlights all sites with outstanding adjudication materials. **Tricia** will be in contact with you by **Friday, March 5** if we still require adjudication materials for any study participants at your site. Outstanding deidentified adjudication materials (clinical notes, images and radiographs) will need to be received no later than **Monday, March 15**.

PLEASE REVIEW THE TABLE BELOW: IF YOUR SITE HAS OUTSTANDING QUERIES OR ADJUDICATION MATERIALS, PLEASE COMPLETE THE REQUIRED TASKS AS SOON AS POSSIBLE AND NO LATER THAN THE DEADLINES LISTED ABOVE!



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	Site	Total Screened Participants	Total Enrolled Participants	Participants Cleaned up to L2 (%)	Participants Cleaned up to L3 (%)	Participants with Outstanding Queries (%)	Participants with Outstanding Adjudication Materials (%)	Participants with Outstanding Follow-Up Data (%)	
1	Juravinski Hospital and Cancer Centre	42	36	42 (100)	42 (100)	o (o)	o (o)	o (o)	
2	Mount Sinai Hospital	59	58	58 (98)	54 (92)	5 (8)	o (o)	o (o)	
3	McGill University Health Centre	56	45	55 (98)	TBD	1(2)	1(2)	o (o)	
4	The Ottawa Hospital	4	4	4 (100)	4 (100)	o (o)	o (o)	o (o)	
5	Vancouver General Hospital	29	5	29 (100)	24 (83)	1(3)	0 (0)	0(0)	
6	Hopital Maisonneuve - Rosemont	49	19	49 (100)	30 (61)	19 (39)	o (o)	o (o)	
7	Saint-François d'Assisse et L'Hotel-Dieu de Quebec	14	14	14 (100)	TBD	o (o)	o (o)	o (o)	
8	Vanderbilt Medical Center	21	19	16 (76)	TBD	5 (24)	1(5)	o (o)	
9	Beth Israel Deaconess Medical Center	1	1	1 (100)	o (o)	1 (100)	o (o)	o (o)	
10	Boston Children's Hospital	5	5	5 (100)	5 (100)	o (o)	1(20)	o (o)	
11	Huntsman Cancer Hospital	22	22	22 (100)	o (o)	8 (36)	2 (9)	o (o)	
12	Memorial Sloan - Kettering Cancer Center	16	15	16 (100)	TBD	o (o)	o (o)	o (o)	
13	Hospital Universitario Austral	20	12	16 (80)	TBD	2 (20)	o (o)	o (o)	
14	Royal Adelaide Hospital	7	2	4 (57)	TBD	3 (43)	2 (29)	2 (29)	
15	University of Connecticut Health Center	0	0	Closed					
16	The Rothman Institute	13	13	13 (100)	13 (100)	o (o)	2 (15)	o (o)	
17	Holden Comprehensive Cancer Center	21	20	21 (100)	1(5)	5 (24)	2 (10)	o (o)	
18	University of Minnesota Medical Center	16	10	16 (100)	15 (94)	1(6)	o (o)	o (o)	
19	Wexner Medical Center	0	0			Closed			
20	Emory Orthopaedics and Spine Center	2	2	o (o)	TBD	2 (100)	o (o)	o (o)	
21	Montefiore Medical Center	12	12	12 (100)	12 (100)	o (o)	1(8)	o (o)	
22	Stanford University Hospital and Clinics	10	9	10 (100)	2 (20)	4 (40)	o (o)	o (o)	
23	Tom Baker Cancer Centre and Foothills Medical Centre	3	3	3 (100)	3 (100)	o (o)	o (o)	o (o)	
24	Sinai Hospital of Baltimore	2	2	2 (100)	o (o)	1 (50)	1 (50)	o (o)	
25	SUNY Upstate University Hospital	10	4	10 (100)	TBD	o (o)	o (o)	o (o)	
26	Maimonides Medical Center	0	0			Closed			
27	University of Pittsburgh Medical Center	0	0			Closed			
28	Massachusetts General Hospital	5	4	5 (100)	5 (100)	o (o)	o (o)	o (o)	
29	Franklin Square Medical Center	5	5	4 (80)	2 (40)	3 (60)	o (o)	o (o)	
30	Albany Medical Center	4	3	4 (100)	TBD	o (o)	o (o)	o (o)	
31	Oregon Health & Science University Hospital	39	36	37 (94)	4 (10)	32 (82)	1(3)	1(3)	
32	Johns Hopkins Hospital	9	9	8 (89)	2 (22)	7 (78)	0 (0)	1 (11)	



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33	Grey's Hospital	16	8	16 (100)	13 (81)	o (o)	o (o)	o (o)	
34	Instituto de Ortopedia e Traumatologia, Instituto do Cancer do Estado de São Paulo	34	34	34 (100)	28 (82)	6 (18)	o (o)	o (o)	
35	Hospital Universitario Vall d'Hebron	9	9	9 (100)	1 (11)	8 (89)	o (o)	o (o)	
36	UCSF Baker Cancer Center	15	11	15 (100)	5 (33)	1(7)	o (o)	o (o)	
37	Cincinnati Children's Hospital	1	1	1 (100)	1 (100)	o (o)	o (o)	o (o)	
38	University of Maryland Medical Center	1	0	1 (100)	1 (100)	o (o)	o (o)	o (o)	
39	UF Health Shands Hospital	34	11	34 (100)	18 (53)	5 (15)	1(3)	0 (0)	
40	Leiden University Medical Center	13	13	11 (85)	2 (15)	1(8)	4 (31)	o (o)	
41	All India Institute of Medical Sciences	85	84	41 (48)	TBD	7 (8)	11 (13)	2 (2)	
42	Froedtert Memorial Lutheran Hospital	3	3	o (o)	TBD	2 (67)	1 (33)	o (o)	
43	Long Island Jewish Medical Center	2	2	o (o)	TBD	o (o)	o (o)	o (o)	
44	Dartmouth-Hitchcock Medical Center	4	4	4 (100)	4 (100)	o (o)	o (o)	o (o)	
45	Saint Louis University Hospital	5	5	4 (80)	TBD	o (o)	o (o)	o (o)	
46	University Medical Centre Groningen	2	2	2 (100)	2 (100)	o (o)	o (o)	o (o)	
47	The Cleveland Clinic	6	6	6 (100)	1 (17)	4 (67)	o (o)	0 (0)	
48	Children's Cancer Hospital Egypt	6	5	6 (100)	2 (33)	o (o)	o (o)	o (o)	
49	Hartford Hospital	2	0	2 (100)	o (o)	2 (100)	o (o)	0 (0)	
50	Hospital de Clinicas de Porto Alegre	5	5	5 (100)	3 (60)	2 (40)	o (o)	o (o)	
51	University of Arkansas for Medical Sciences	0	0	Closed					
52	UCLA Ronald Reagan Medical Center	2	1	2 (100)	2 (100)	o (o)	o (o)	o (o)	
53	Universitätsklinikum Graz	10	6	10 (100)	7 (70)	3 (30)	0 (0)	o (o)	
54	Singapore General Hospital	3	3	3 (100)	o (o)	3 (100)	0 (0)	o (o)	
55	University of California Davis Medical Center	1	1	1 (100)	1 (100)	o (o)	o (o)	o (o)	

### PARITY Methods Centre Contacts

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