

## PROPHYLACTIC ANTIBIOTIC REGIMENS IN TUMOR SURGERY

**PARITY Newsletter** 

October 2019 • Edition 27

# Recruitment Update

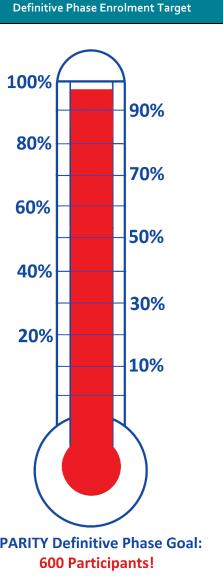
#### PARITY Trial is only 8 participants away from the enrolment target!



Congratulations to Dr. Shah Alam Khan at the All India Institute of Medical Sciences for enrolling three more PARITY participants and to Dr. Benjamin Miller and his research team at Holden Comprehensive Cancer Center for enrolling two more PARITY participants since the last update.

We are pleased to report that as of 3 October 2019, 592 participants have been enrolled in the PARITY trial.

| Site  | Country      | Enrolled Since<br>Last Update | Enrolled to Date | Definitive Phase Enrol |  |  |
|---|--------------|-------------------------------|------------------|------------------------|--|--|
| Juravinski Hospital and Cancer Centre         | Canada       | -                             | 36               |                        |  |  |
| Mount Sinai Hospital                          | Canada       | -                             | 56               |                        |  |  |
| McGill University Health Centre               | Canada       | -                             | 45               |                        |  |  |
| The Ottawa Hospital                           | Canada       | -                             | 4                | 100%                   |  |  |
| Vancouver General Hospital                    | Canada       | -                             | 5                | 100%                   |  |  |
| Hôpital Maisonneuve-Rosemont                  | Canada       | -                             | 19               |                        |  |  |
| Hôpital Hôtel-Dieu                            | Canada       | 1                             | 13               |                        |  |  |
| Vanderbilt Orthopaedic Institute              | USA          | -                             | 19               | 000/                   |  |  |
| Beth Israel Deaconess Medical Center          | USA          | -                             | 1                | 80%                    |  |  |
| Boston Children's Hospital                    | USA          | -                             | 5                |                        |  |  |
| Huntsman Cancer Institute                     | USA          | 1                             | 22               |                        |  |  |
| Memorial Sloan Kettering Cancer Center        | USA          | -                             | 15               |                        |  |  |
| Hospital Universitario Austral                | Argentina    | 1                             | 12               | 60%                    |  |  |
| Royal Adelaide Hospital                       | Australia    | -                             | 2                | 00/0                   |  |  |
| University of Connecticut Health Center       | USA          | -                             | -                |                        |  |  |
| The Rothman Institute                         | USA          | -                             | 13               |                        |  |  |
| Holden Comprehensive Cancer Center            | USA          | 2                             | 19               | 400/                   |  |  |
| University of Minnesota Medical Center        | USA          | -                             | 10               | 40%                    |  |  |
| Wexner Medical Center                         | USA          | -                             | -                |                        |  |  |
| Emory University Orthopedics and Spine Center | USA          | -                             | 2                |                        |  |  |
| Montefiore Medical Center                     | USA          | -                             | 12               |                        |  |  |
| Stanford University Health Care               | USA          | 1                             | 9                | 20%                    |  |  |
| Foothills Medical Centre                      | Canada       | -                             | 3                |                        |  |  |
| Sinai Hospital of Baltimore                   | USA          | -                             | 2                |                        |  |  |
| SUNY Upstate University Hospital              | USA          | -                             | 4                |                        |  |  |
| Maimonides Medical Center                     | USA          | -                             | -                |                        |  |  |
| University of Pittsburgh Medical Center       | USA          | -                             | -                |                        |  |  |
| Massachusetts General Hospital                | USA          | -                             | 4                |                        |  |  |
| Franklin Square Medical Center                | USA          | -                             | 5                |                        |  |  |
| Albany Medical Center                         | USA          | -                             | 3                |                        |  |  |
| Oregon Health & Science University Hospital   | USA          | -                             | 36               |                        |  |  |
| Johns Hopkins Hospital                        | USA          | -                             | 8                |                        |  |  |
| Grey's Hospital                               | South Africa | -                             | 8                |                        |  |  |
| Instituto de Ortopedia e Traumatologia        | Brazil       | -                             | 33               |                        |  |  |
| Hospital Vall d'Hebron                        | Spain        | -                             | 8                |                        |  |  |
| UC San Francisco Medical Center               | USA          | -                             | 10               | PARITY Definitive P    |  |  |
| Cincinnati Children's Hospital                | USA          | -                             | 1                |                        |  |  |
| University of Maryland Medical Center         | USA          | -                             | -                | 600 Participa          |  |  |
| University of Florida Health Shands Hospital  | USA          | -                             | 10               |                        |  |  |



| Leiden University Medical Center            | Netherlands | -  | 13  |
|---|-------------|----|-----|
| All India Institute of Medical Sciences     | India       | 4  | 84  |
| Medical College of Wisconsin                | USA         | -  | 3   |
| Northwell Health                            | USA         | -  | 2   |
| Dartmouth-Hitchcock Medical Center          | USA         | -  | 4   |
| Saint Louis University Hospital             | USA         | -  | 4   |
| University Medical Center Groningen         | Netherlands | -  | 2   |
| The Cleveland Clinic                        | USA         | -  | 6   |
| Children's Cancer Hospital Egypt            | Egypt       | -  | 5   |
| Hartford Hospital                           | USA         | -  | -   |
| Hospital de Clínicas de Porto Alegre        | Brazil      | -  | 5   |
| University of Arkansas for Medical Sciences | USA         | -  | -   |
| UC Los Angeles Medical Center               | USA         | -  | 1   |
| Medical University Graz                     | AUT         | -  | 5   |
| Singapore General Hospital                  | SGP         | -  | 3   |
| UC Davis Medical Center                     | USA         | -  | 1   |
|   | Total       | 10 | 592 |

closed site

## **PARITY, The Final Countdown**



# PLEASE DO NOT RANDOMIZE UNTIL THE PATIENT HAS SIGNED A CONSENT FORM AND SURGERY HAS COMMENCED!

If an incorrect Participant ID or tumor location is entered when randomizing, please notify the Methods Centre **IMMEDIATELY**.

\*Please do not re-randomize the participant\*

## **PARITY Success Bulletin**

#### Final PARITY Recruitment

There are now less than 10 participants to enroll to reach the PARITY targeted sample size! Once the 595<sup>th</sup> PARITY participant has been enrolled, access to the randomization system will be removed. An email will be sent out to inform you of this change. Please contact the methods center if you have a participant to enroll in the PARITY trial during this time and temporary access will be provided to randomize one of the 5 remaining participants.

Please **continue to recruit and randomize patients** as normal until the Methods Center notifies you of this change.

#### PARITY Presented at ISOLS

The PARITY Methods Center team attended the International Society of Limb Salvage 2019 Annual Meeting to present an update on the PARITY trial. The PARITY Investigators are listed as the author of this presentation. The details for your CVs are as follows:

**Title:** The Prophylactic Antibiotic Regimens In Tumor Surgery (PARITY) International Randomized Controlled Trial: Completion of Enrolment and Preparation for Publication

**Authors:** The PARITY Investigators

Meeting: International Society of Limb Salvage 2019 Annual

Meeting

Date: September 11-14, 2019

City: Athens, Greece



## **PARITY Adjudication**

Event adjudication continues for the trial. **Naveen Khan** may contact you requesting de-identified adjudication materials (chart notes, images and radiographs) for participants that you have reported as having any of the listed study events.

#### **PARITY Collaborative Celebrations**

Thank you to all those who joined us in our recent collaborative dinners to celebrate the success of the PARITY trial. We shared a delicious meal at Cookoovaya in Athens, Greece at the 2019 ISOLS Annual meeting, and at Q Restaurant in Portland, Oregon, at the MSTS 2019 Annual Meeting. We look forward to continuing our prosperous collaborations with you!





## PARITY DSMB Meeting

The DSMB Annual Meeting took place on 11 June 2019. The DSMB approved continuation of the PARITY trial for the next year.

If your site requires a copy of the formal recommendation from the DSMB, please contact the **Methods Centre**. The next scheduled DSMB meeting will occur once PARITY enrolment is complete!

# **Data Cleaning Deadlines**

As the PARITY trial completes enrolment, we are focusing efforts on data cleaning in preparation for publication. Please refer to the deadlines below to ensure all patients are query free in iDataFax at the appropriate times. **Victoria** will continue to email detailed queries, however you may check ongoing queries in the iDataFax database (refer to PARITY Newsletter February 2019 Edition 19). If you have any questions regarding queries on a patient, please contact **Victoria**.

Data Cleaning Deadline for Patients ≤ 2015: September 30, 2019

Data Cleaning Deadline for 2016 Patients: December 31, 2019

Data Cleaning Deadline for 2017 Patients: January 31, 2020

Data Cleaning Deadline for 2018 Patients: April 30, 2020

| Country      | Total No. of<br>Participants<br>Enrolled |       | Total No. of Participants with Complete Follow-Up Data |      | Total No. of<br>Participants<br>Withdrawn:<br>Death |      | Total No. of Participants Withdrawn: Lost to Follow- Up or Other Reason |      | Total No. of<br>Participants<br>Overdue |      | Total No. of<br>participants in<br>Active Follow-<br>Up |       |
|--------------|--|-------|--|------|---|------|---|------|---|------|---|-------|
|              | N  | %     | N  | %    | N   | %    | N   | %    | N                                       | %    | N   | %     |
| Argentina    | 12                                       | 2.1   | 8  | 66.7 | 2   | 16.7 | 0   | 0.0  | 0                                       | 0    | 2   | 16.7  |
| Australia    | 2  | 0.3   | 0  | 0.0  | 0   | 0.0  | 1   | 50.0 | 1                                       | 50.0 | 0   | 0.0   |
| Austria      | 5  | 0.9   | 0  | 0.0  | 0   | 0.0  | 0   | 0.0  | 0                                       | 0.0  | 5   | 100.0 |
| Brazil       | 38                                       | 6.5   | 14   | 36.8 | 3   | 7.9  | 4   | 10.5 | 17                                      | 44.7 | 3   | 7.9   |
| Canada       | 181                                      | 30.9  | 104  | 57.8 | 31  | 17.2 | 1   | 0.6  | 15                                      | 8.3  | 30  | 16.6  |
| Egypt        | 5  | 0.9   | 0  | 0.0  | 0   | 0.0  | 0   | 0.0  | 4                                       | 80.0 | 1   | 20.0  |
| Spain        | 8  | 1.4   | 4  | 50.0 | 1   | 12.5 | 0   | 0.0  | 2                                       | 25.0 | 1   | 12.5  |
| India        | 84                                       | 14.2  | 25   | 31.3 | 5   | 6.3  | 6   | 7.5  | 6                                       | 7.5  | 42  | 50.0  |
| Netherlands  | 15                                       | 2.5   | 0  | 0.0  | 0   | 0.0  | 0   | 0.0  | 7                                       | 46.7 | 8   | 53.3  |
| Singapore    | 3  | 0.5   | 0  | 0.0  | 0   | 0.0  | 0   | 0.0  | 0                                       | 0.0  | 3   | 100.0 |
| USA          | 231                                      | 39.0  | 89   | 39.2 | 16  | 7.0  | 8   | 3.5  | 66                                      | 29.1 | 52  | 22.5  |
| South Africa | 8  | 1.4   | 1  | 12.5 | 2   | 25.0 | 0   | 0.0  | 3                                       | 37.5 | 2   | 25.0  |
| Total        | 592                                      | 100.0 | 245  | 42.1 | 60  | 10.3 | 20  | 3.4  | 118                                     | 21.0 | 149   | 25.2  |

## **PARITY Methods Centre Contacts**

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