

Tata Medical Center

14 Major Arterial Road (EW)
Newtown, Rajarhat, Kolkata - 700 160
Tel.: + 91 33 66057000, Email : info@tmckolkata.com
www.tmckolkata.com



Date: 17-July-2026

To,

The Head of the Institution,

Tata Medical Center,
14, Major arterial Road (E-W) Rajrhat,
New Town, North 24 Parganas, Kolkata, PIN 700160

Reference: GSP 402-301 (SHR-A1811-315_Extension) Study

Study Title: An Open-label, Randomized, Multicenter Phase III Clinical Trial of SHR-A1811 Versus Investigator-selected Chemotherapy for Platinum-resistant Relapsed Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.

Subject: Submission of study documents for review and approval.

Dear sir,

Please find below the list documents for the review and approval:

1. Protocol_GSP 402-301 (SHR-A1811-315_Extension)_Version: 3.0 dated 18-Dec-2025
2. Investigator's Agreement_GSP 402-301 (SHR-A1811-315_Extension)_Version 3.0_ dated 18-Dec-2025_Signed and dated by Dr. Arnab Bhattacharjee on 22-Dec-2025.
3. Investigational Brochure_Version 6.0_dated 04-Jul-2025
4. Investigator Undertaking by PI_Signed on.
5. GSP 402-301(SHR-A1811-315_Extension)_PIS-ICF_Core_1.0_India_1.0 dated 06-Jan-2026_Customised for Dr. Arnab Bhattacharjee on 27-Jan-2026 (English)
6. GSP 402-301 (SHR-A1811-315_Extension)_PIS-ICF_Core_1.0_India_1.0_Bengali_1.0 dated 17-Jan-2026_Customised for Dr. Arnab Bhattacharjee on 28-Jan-2026
7. GSP 402-301 (SHR-A1811-315_Extension)_PIS-ICF_Core_1.0_India_1.0_Bengali_1.0 dated 17-Jan-2026_Customised for Dr. Arnab Bhattacharjee on 28-Jan-2026_Back translated from Bengali to English on 28-Jan-2026
8. GSP 402-301(SHR-A1811-315_Extension)_PIS-ICF_Core_1.0_India_1.0_Hindi_1.0 dated 13-Jan-2026_Customised for Dr. Arnab Bhattacharjee on 28-Jan-2026
9. GSP 402-301(SHR-A1811-315_Extension)_PIS-ICF_Core_1.0_India_1.0_Hindi_1.0 dated 13-Jan-2026_Customised for Dr. Arnab Bhattacharjee on 28-Jan-2026_Back translated from Hindi to English on 28-Jan-2026

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10. GSP 402-301 (SHR-A1811-315_Extension)_PIS-ICF_Foward and backward translation certificates (Bengali and Hindi)_Translation dated 28 Jan 2026
11. GSP 402-301 (SHR-A1811-315_Extension)_Consent Form for HER2 Testing_Core_1.0_India_1.0 dated 08-Jan-2026 (English)
12. GSP 402-301 (SHR-A1811-315_Extension)_Consent Form for HER2 Testing_Core_1.0_India_1.0_Bengali_1.0 dated 17-Jan-2026
13. GSP 402-301 (SHR-A1811-315_Extension)_Consent Form for HER2 Testing_Core_1.0_India_1.0_Bengali_1.0 dated 17-Jan-2026_Back Translated from Bengali to English on 17-Jan-2026
14. GSP 402-301 (SHR-A1811-315_Extension)_Consent Form for HER2 Testing_Core_1.0_India_1.0_Hindi_1.0 dated 13-Jan-2026
15. GSP 402-301 (SHR-A1811-315_Extension)_Consent Form for HER2 Testing_Core_1.0_India_1.0_Hindi_1.0 dated 13-Jan-2026_Back Translated from Hindi to English on 13-Jan-2026
16. GSP 402-301 (SHR-A1811-315_Extension)_Consent Form for HER2 Testing_ Forward and backward translation certificates (Hindi)_Translation dated 13 Jan 2026
17. GSP 402-301 (SHR-A1811-315_Extension)_Consent Form for HER2 Testing_ Forward and backward translation certificates (Bengali)_Translation dated 17 Jan 2026
18. GSP 402-301(SHR-A1811 315_Extension)_ EQ-5D-5L and FOSI scales- English, Hindi, Bengali with translation certificates of respective languages.
19. CV, MRC and GCP of Dr. Arnab Bhattacharjee_signed dated on 02 Dec 2025
20. GSP 402-301(SHR-A1811 315_Extension)_Final CRF_Version 0.1_dated 27- MAR-2026
21. GSP 402-301(SHR-A1811 315_Extension)_Draft CTA
22. GSP 402-301(SHR-A1811 315_Extension)_DCGI submission dated 26 Dec 2025
23. GSP 402-301(SHR-A1811 315_Extension)_Insurance Certificate_dated 02-July-2026.
24. GSP 402-301(SHR-A1811 315_Extension)_Patient Accrual method
25. GSP 402-301(SHR-A1811 315_Extension)_DCGI approval letter dated 25 June 2026
26. GSP 402-301(SHR-A1811 315_Extension)_CTRI certificate 06-July-2026
27. RSD application

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28. CV, MRC, GCP of the investigators

In case of any assistance, kindly let me know.

Thank you,

Regards,

Dr. Arnab Bhattacharjee
Principal Investigator

I hereby acknowledge the receipt of above mentioned document on behalf of ethics committee

Date received

Signature

Name of the personnel

Seal of the Ethics committee

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To,
The Chairman,
Tata Medical Center,
Institutional Review Board
14, Major arterial Road (E-W) Rajrhat,
New Town, North 24 Parganas, Kolkata, PIN 700160
Date: 17- July-2026

Study Title: - An Open-label, Randomized, Multicenter Phase III Clinical Trial of SHR-A1811 Versus Investigator-selected Chemotherapy for Platinum-resistant Relapsed Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer.

Reference: - GSP 402-301 (SHR-A1811 315_Extension) Study

Subject: - Patient Accrual method for above reference study.

This is to document that for above mentioned study following patient accrual method will be utilized.

1. Patients will be identified by PI/Sub-I from his/her consultations at the site as well as from other practicing OPD's.
2. Site may identify patients from their database available at the site.
3. Site may get patients via referral mode also.

This is to confirm that all study related procedures including signing of Informed Consent Form for above identified potential patients will be done at study site only

Thanking You,
Your Sincerely,

Dr. Arnab Bhattacharjee

Principal Investigator