

To,

Dr. Arnab Bhattacharjee
Tata Medical Center,
Dept. of Medical Oncology 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: EC Submission of study documents to Ethics Committee for review and approval.

Dear sir,

Please find below the list documents for the Ethics Committee 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 19-Dec-2025.
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
10. GSP 402-301 (SHR-A1811-315_Extension)_PIS-ICF_Forward 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_Foward and
backward translation certificates (Hindi)_Translation dated 13 Jan 2026
17. GSP 402-301 (SHR-A1811-315_Extension)_Consent Form for HER2 Testing_Foward 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)_Draft CRF_Version 0.1_dated 23 Dec 2025
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 09-Feb-2026.
24. GSP 402-301(SHR-A1811 315_Extension)_Patient Accrual method

Look forward to hearing from you and thanking you for your consideration.

Rashi
16 Feb 26

From,

Rashi Pandey

Senior Clinical Research Associate

Ad
17/7/26