

23 June 2025

To: Regulatory Affairs Division  
National Medicines Agency

Subject: Submission of Clinical Trial Application – Protocol CTL-2025-001

Dear Sir/Madam,

On behalf of PharmaNova Inc., we are pleased to submit the application package for the Phase IIb clinical trial enrolling 150 patients to evaluate Drug X.

Documents included in this submission:

1. Protocol CTL-2025-001 Version 1.0
2. Investigator's Brochure Version 2.0
3. Informed Consent Form Version 1.0
4. Statistical Analysis Plan Version 1.0

We confirm that the package is complete and complies with current regulations.

Sincerely,

Jane Doe  
Director, Regulatory Affairs  
PharmaNova Inc.