**APH301 Final Year Project**

**Supervisor Choice Form**

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| Form A: Basic Information | | | |
| Student Name:  Xiaoyu. Luo | Student ID:  2144079 | | Student Email Address:  Xiaoyu.luo21@student.xjtlu.edu.cn |
| Supervisor Name:  Xiaoyu. Tang | Supervisor Email:  Xiaoyu.Tang@xjtlu.edu.cn | | Supervisor’s Department:  AoPHA Faculty |
| External Supervisor[[1]](#footnote-1) (Yes/No): No | If yes, the name of internal supervisor[[2]](#footnote-2): | | |
| Form B: FYP Proposal | | | |
| Tentative Project Title:  **Evaluation of concordance between disease response assessments by investigator and by BICR in hematology clinical trials** | | | |
| Project Proposal (200 words):  The project aims to investigate the concordance between disease response assessments made by investigators and those conducted by blinded independent central review (BICR). BICR assessments are commonly used in oncology clinical trials to mitigate potential bias in local evaluations, especially in open-label studies. However, BICR assessments can be costly, time-consuming, and resource-demanding. Sponsors must manage and monitor data for BICR review. Any delays in BICR assessment can impact regulatory submissions. While several meta-analyses have examined the correlations between treatment effect estimates based on response data assessed by BICR and investigators, most of these studies focus on solid tumors but no studies have specifically focused on hematology. In this project, meta-analyses will be conducted to evaluate the concordance between BICR and investigator assessments in terms of progression-free survival (PFS) and objective response in hematology clinical trials. Additionally, meta-regression will be used to assess factors that may influence the concordance, such as sample size, trial design (open-label or blinded), and indication. If consistent treatment effects are found, we may consider reducing the frequency of BICR assessments. Conversely, if factors leading to discordance are identified, we may need to evaluate the necessity of BICR for specific study designs and potentially include BICR assessment as a sensitivity analysis. | | | |
| Explain why this proposal is appropriate for final year project in the major of applied statistics[[3]](#footnote-3) (100 words):  The focus of this project is on pharmaceuticals’ concerns. From this project, the student will gain insight into the processes and statistical methods used in oncology clinical trials by reviewing a substantial number of clinical trial articles and extracting essential information from those literatures. Additionally, the student will have opportunities to identify and apply appropriate statistical methods to synthesize and analyze clinical trial data they have extracted. This project will demonstrate how the statistical methods learned in class can be applied to real-world problems. | | | |
| Form C: Testimony and Signature | | | |
| Testimony for the student:  It’s my choice to select Xiaoyu Tang as my final year project supervisor. I will work towards the goals set by the FYP proposal above and ensure timely progress towards the completion of my FYP, subject to the protocols of APH301. | | | |
| Student’s signature: | | Date of signature: 2024.8.22 | |
| Testimony for the supervisor:  It’s my choice to supervise Xiaoyu Luo for his/her final year project in the major of applied statistics. I will exercise my due diligence to ensure that the student makes timely progress towards the completion of his/her FYP, subject to the protocols of APH301. | | | |
| Supervisor’s signature: | | Date of signature: 2024.8.23 | |
| Any comments from the module leader of APH301: | | | |

1. External supervisor refers to a faculty member outside of the academy of pharmacy (AoP) or the school of math and physics (SMP). [↑](#footnote-ref-1)
2. Internal supervisor is needed in this case and needs to be a faculty member in AoP or SMP. [↑](#footnote-ref-2)
3. FYP should not be purely based on wet labs and should have a focus on data analysis and statistical modeling. The module leader reserves the right to reject proposals that do not fit the scope of applied statistics. [↑](#footnote-ref-3)