

19/11/2019

PI: Kristian Aquilina

R&D number: 19BI18

Title: Algorithmic Machine Learning on Ultrasound Images for Hydrocephalus Prediction in Neonates (MLHP)

Dear Kristian,

Thank you for your application to the Clinical Research Adoptions Committee (CRAC) which was reviewed on 12th November 2019. Thank you to William Dawes and Joseph Davids for attending the meeting to give the committee an opportunity to ask further questions. We were pleased to review your application and we recognise the importance of your project.

This is a study applying open source software to test algorithmic machine learning in identifying hydrocephalus from ultrasound images in neonates. Initial study would involve 50 images to establish accuracy of the algorithm. Investigators are part on the clinical team and have access to images already and the images will be fully anonymised.

It was established during the meeting that this is a simple proof-of-concept study and therefore the committee have no major objections to the conduct of this project at GOSH. However, some issues outlined below require clarification before full CRAC Approval can be granted.

1. The numbers involved in the study seemed very low. Typically thousands of images are required to evaluate machine learning algorithms. Please cross-reference similar published work to justify the low numbers <100 involved.
2. Investigators need to establish whether ethical approval is required for this study. As investigators are already part of the clinical team and have direct access to the images, they can do anonymization directly. However, in this instance ethics will be necessary. The committee suggested speaking to Digital Research Environment (DRE) team who can process and anonymise data on behalf of investigators in which case ethical approvals would not be necessary, particularly if a larger subsequent study is planned.

3. Hydrocephalus has not been defined in the study. Is a subjective assessment going to be used (in which case, how was this made) or is an objective measure of CSF volume going to be assessed (e.g. ventricular index on cranial US). The definition of “ground truth” of normal and abnormal will clearly affect the algorithm’s success.
4. Clearly the accurate interpretation of imaging regarding hydrocephalus will require imaging support from both Radiology and the PACS team, where there is growing AI interest. It would be useful to link with both of these teams and the committee note there is current no Radiologist in the research team.
5. Where does the intellectual property for the algorithm sit ? If it is for future commercial gain, then there will need to be further discussion with R&D about the use of GOSH data where there is no GOSH IP involvement.
6. Please clarify the funding required for PACS involvement in anonymising imaging etc.

Decision: Resubmission

Regards,



Dr Owen Arthurs
Chair
Clinical Research Adoption Committee