Executive Summary

Title: The use of Artificial intelligence and Real World Data for the prediction of visual and anatomical outcomes in Diabetic Macular Oedema within the NHS

One of the leading causes of blindness around the world is diabetic retinopathy and a complication it causes called diabetic macular oedema (DMO)[1].

While there have been advances in the treatment for DMO, not all patients have the same prognosis. The rate of progression and the response to treatment vary between patients, as do the final visual outcomes[2]. Disease progression and response to treatment are often monitored by using a non-invasive imaging technique called optical coherence tomography (OCT) that acquires high-resolution three-dimensional images of the retina. Currently, there are limited predictive models to identify treatment response and estimate future final visual and / or anatomical outcomes for patients[1].

In this partnership, we aim to develop artificial intelligence (AI) models applied to DMO that allow:
1) *The identification of imaging biomarkers that reflect the disease pathophysiology.*
2) *Help identify disease change and progression.*
3) *Accurately measure and predict response to treatment(s).*

Specifically, this project will assess whether AI models (deep neural networks) using clinical data and imaging data from clinical trials as well as real-world data (RWD) can be beneficial in the prediction of visual and anatomical outcomes, enabling deeper insight into the development of optimal patient care pathways in the future.

Organisations involved:
Roche Products Ltd, Newcastle University, and South Tyneside and Sunderland NHS Foundation Trust are parties in this Collaborative Working Project. Newcastle University will provide both the data infrastructure to process *anonymised* patient information and academic expertise for the purpose of the collaboration. South Tyneside and Sunderland NHS Foundation Trust will provide clinical and scientific expertise and will provide the annonymised data needed for the project. Roche will second staff to Newcastle University to work in partnership with The University of Newcastle Upon Tyne's academics and researchers to deliver the project. Roche will also provide funding for the project.

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[1] Amoaku *et al., Diabetic retinopathy and diabetic macular oedema pathways and management: UK Consensus Working Group*. Eye (2020) Jun;34 (Suppl 1):1-51. Erratum in: Eye (Lond). 2020 Oct;34(10):1941-1942.
[2] Ashraf *et al., Predicting outcomes to anti-vascular endothelial growth factor (VEGF) therapy in diabetic macular oedema: a review of the literature*. British Journal of Ophthalmology (2016);100:1596-1604.

Benefits to patients:
This project will assess whether AI models, using RWD that extract OCT structural biomarkers, can be beneficial in the prediction of functional visual and anatomical outcomes, enabling deeper insight into patient care in the future.

Benefits to the NHS:
All arising Intellectual Property Rights (IPRs) will be owned by Newcastle University, who will take all necessary steps to share and disseminate IPRs and to publish in accordance with a creative commons license. This approach will give all users (including the NHS) full access, use and permissions to re-use the IPRs indefinitely, with the aim of accelerating clinical learnings within ophthalmology. Roche believes that this approach will help to break down existing barriers to the rapid uptake of technological advances across the NHS.

Benefits to Roche:
Roche wish to better understand the quality and data engineering challenges within the NHS and seize the opportunity to develop real-world AI models within a healthcare setting. Roche are committed to demonstrating the value that working in a collaborative partnership with the NHS can bring, be it through early identification of patients and/or optimisation of their clinical pathway and improved treatment outcomes.

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