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Dr Brandon Gallas

Re: Support for Critical Path Proposal

Dear Dr Gallas

I'm writing this letter in support of your Critical Path proposal entitled "High-throughput truthing of microscope slides to validate artificial intelligence algorithms analyzing digital scans of same slides: data (images + annotations) as an MDDT".

As you know, at University of Leeds we have been researching digital pathology for over 15 years, with one of the largest digital pathology image repositories in the world (386,000 slides, 150 Terabytes of image data). In our hospital at Leeds Teaching Hospitals NHS Trust we have transitioned to a fully digital workflow for clinical pathology diagnosis, scanning over 1000 slides a day, and 6 of our pathologists working fully digitally for primary diagnosis, with the other 35+ following over the next 12 months. We prioritise an evidence based approach to digital pathology, with over 80 papers specifically on digital pathology including work on clinical validation, colour and human computer interaction. Our work has led to the UK national guidelines for digital pathology and significant partnerships with several vendors including Leica Biosystems, Roche and Sectra.

We think your proposal is timely and practical. The FDA/CDRH Medical Device Development Tool program seems ideal to demonstrate how the clinical care community can impact the evaluation of AI in digital pathology and gain trust in the use of AI tools. The pathologists can have ownership of their contributions – their annotations – by creating an FDA-qualified validation dataset to be used by any and all algorithm developers. We are particularly impressed by the leading position that FDA have taken in digital pathology and the coming AI revolution in healthcare, and your work furthers that advanced position for your organisation.

We would be pleased to support you in any way we can, including:

- Access to our images, data, and staff
- Input on experimental design

- Participation in your experimental work
- Supporting and co-organising an event at the UK Pathological Society in 2-5 July 2018 at which we could run a data-gathering exercise

We remain at your service for any areas where my expertise may be of value to your research.

Sincerely



Darren Treanor BSc (Computing) PhD FRCPath
Consultant Pathologist/ Honorary Clinical Associate Professor