

## Developing a novel fluorescence-based biopharmaceutical quality control technology

*A Business interaction voucher from BioProNET has enabled Christopher Pudney from the University of Bath to partner with Bath ASU to develop a new method for quality control testing of biologics that could be faster and cheaper than current approaches.*

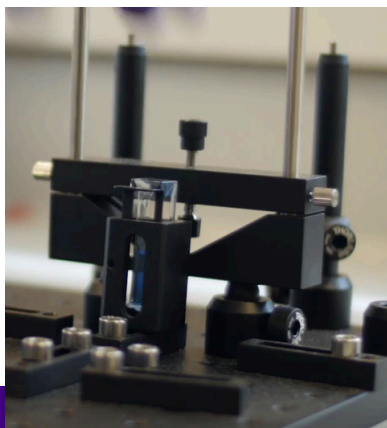
### AIMS

There are a limited number of approaches to perform quality control analysis of biological molecules. We will work with partner company Bath ASU to develop a novel technology — based on quantification of the fluorescence edge shift phenomenon — that gives a library of spectroscopic fingerprints for different biopharmaceuticals and accurately quantifies subtle changes to protein structure. We will test a range of biopharmaceuticals, allowing us to develop our technology to improve speed and accuracy and also to establish the limits of sensitivity.

### KEY RESULTS

We looked at 12 monoclonal antibodies (including humanised and fully human) using our fluorescence edge shift technology. We benchmarked against circular dichroism and dynamic light scattering and found that fluorescence edge shift technology had a similar sensitivity to both traditional approaches, but that we could combine the measurement power of both approaches. So we could measure unfolding (normally assessed by circular dichroism) and aggregation (normally assessed by dynamic light scattering). Our measurements were not destructive, were faster and were at least as accurate as these approaches. So we found our approach could potentially replace these other approaches making quality control faster and less expensive. Most importantly, we have been able to show our approach can actually predict the stability of antibodies and this opens up a whole new range of possibilities for our approach.

*“The BiV let has have a meaningful partnership with an industrial collaborator. The BiV has moved the commercial potential of our technology on immensely and has been key for us going forward.”*



### OUTCOMES

1. Patent filing (UK Patent Application No. 1604640.1).
2. Manuscript in review with industrial partner.
3. Presentation at the 2nd International Antibody Validation Meeting
4. EPSRC funding as part of seed-corn funding for a GCRF project
5. EPSRC Impact Acceleration Account award
6. Short film: <https://youtube/kHdZBy5xJ2A>