

## Comments from Onyvax Ltd

As a UK SME that has successfully conducted clinical trials in this country and is currently starting up a Phase IIb study in several European countries, we have several observations about bottlenecks in the system that we feel need to be resolved urgently to ensure efficient use of health research funding:

1. The new Clinical Trials Agreement is still not in place. A standard CTA that is accepted by all UK institutions, with no customization, is required if we are to avoid multiple rounds of negotiation (and legal fees) associated with every single trial centre.
2. Hospital Pharmacies appear to be overstretched to the point where they have become inhibitory to trial initiation. This appears partly due to resource constraints (budgetary pressures within the NHS), and partly to multiple regulatory systems (IMP licenses, the Pharmacy QC Network, Health & Safety) that present complex interactions which can, and in some cases, already have become a toxic burden.
3. COREC has helped centralize the Ethics process, but there are still too many individual committees, each with its own distinct approach and loco-regional priorities. It would be better to have a single, professional Ethics committee, possibly under the wing of either MHRA or NICE.
4. There is still no central R&D process. This is another rate limiting step which has to be dealt with on an institution-by-institution basis. Again, this could be handled by a professional committee in MHRA or NICE.

Although UKCRC and its subsidiary networks are addressing some of these issues, we really can not stress too highly the need to resolve the bottlenecks (and, undoubtedly, the others that will be unmasked when the above are no longer rate-limiting). Currently, it is proving an order of magnitude more feasible to initiate a trial in other European sites than in the UK.

Without rapid improvement, there is a real risk that we will simply lose the capacity and experience base to allow efficient and effective clinical research in this country. Furthermore, there seems little point trying to fund additional studies in the UK when the basic infrastructure is not fit for purpose as this will inevitably result in inefficiency and waste.

We'd be happy to provide further detail,

Regards,

Anthony Walker

---

Anthony Walker, PhD  
CEO  
Onyvax Limited