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VIEWS AND REVIEWS

Bureaucracy is strangling clinical research

Legislation has not appreciably changed since 2001, but those administering it or working within it are producing more and more bureaucratic demands

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Clinical research is fundamental to the advancement of medical practice and improving outcomes for patients. This is without question, but evidence based medicine requires the generation of evidence and it is this process that has evolved to a place where it may become self defeating.

Year after year, clinical research teams and investigating physicians are subjected to an exponential growth in the administrative burden, paperwork, and regulation associated with clinical trials. The law has not appreciably changed since 2001, but those administering it or working within it are producing more bureaucratic demands. The universal explanation for this increasing workload is that it represents "good clinical practice" and is there to support the safety of the patient and the integrity of the research. It is impossible to disagree with those aims, however this deluge of bureaucracy is in danger of having the opposite effect.

We are inundated with multiple amendments, many of which are of no clinical relevance; we receive information on side effects that have been known about for years; we get notification of suspected unexpected serious adverse reactions that are neither serious nor unexpected; and we field countless clinically insignificant queries. All of these have to be acknowledged through online, password protected systems that are different for different trials and can mean having to do this multiple times if you are running many studies with the same drug.

Many of these trials are run by contract research organisations that work as intermediaries between drug companies and researchers and have created an industry that has developed many of these processes. More often than not, the representatives of these companies have little knowledge of diseases relevant to the trials, which leads to endless unnecessary questions and further paperwork. These processes take up an inordinate amount of time and help explain some of the rising costs of clinical trials and new drugs.

One unintended side effect of both uncontrolled bureaucracy and the increasing cost of clinical trials will be the disappearance of independent academic clinical research or the inability of new investigators to engage in clinical research.

This article has been signed by almost 1000 senior researchers in haematology from across Europe (for a full list of signatories see https://blogs.bmj.com/bmj/2019/02/26/simon-rule-and-steven-legouill-bureaucracy-is-strangling-clinical-research). Most have been involved with clinical research for years and are fortunate in having research teams that help with this increasing workload. For new investigators, without any infrastructure to support them, clinical research has become too time consuming and challenging to engage with.

Where are the regulators in this process? Unfortunately, they have set the tone with their own inspection processes and bureaucratic systems. The justification is always that this is about patient safety. Many of us believe, however, that research is less safe today; the deluge of unimportant information that follows the opening of a trial means that the truly important signals are lost and the length of, and language used in, consent forms mean that patients no longer truly understand what they are getting involved with. Is it "good clinical practice" to ask a patient to re-consent to a trial (often multiple times), to acknowledge new side effects of a drug that they never received, or to re-consent to having fewer investigations? This continues even after they are no longer on the study. Consent forms are dozens of pages long, often confuse patients, and on occasions can scare them. The impact of this goes unrecognised, but any challenge to this process is regarded as tantamount to serious professional misconduct. This is setting a tone that many investigators are no longer willing to tolerate.

The Declaration of Helsinki and the International Conference on Harmonisation-Good Clinical Practice are there to provide a framework to ensure the quality, integrity, and safety of all research. These principles are fundamental and beyond question: they have not changed. The processes used to ensure compliance with these principles, however, have been allowed to run out of control and are in danger of defeating their purpose. We believe it is time for our health authorities to review the whole system in order to truly ensure patient safety and medical progress. This review should involve pharmaceutical companies, independent research organisations, charitable organisations that fund research, clinical teams running studies, and, most

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importantly, patients. We feel a new framework is needed—one that changes the way research is administered to rebalance the system away from an industry that has created most of it, back to a focus on patients and those with the primary responsibility of looking after them.

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