Blog post

New to regulations? Some places you might want to start off

If you're building digital healthtech, you'll eventually need to read all our content – and the sooner the better. But if you're looking for a manageable chunk to cover in 2 weeks, and use to upskill the rest of your team, here's where you might want to begin:

First, read about how to develop your value proposition. You've likely already researched this in depth, but it does have regulatory and evidence generation implications. For example, your value proposition and intended purpose should be aligned. But sometimes they end up being in conflict, because value propositions often change over time as you discover more about the needs of patients and providers. It's vital that your intended purpose statement is still valid and aligns with your value proposition. This is the case for technologies that start out as medical devices, and also for technologies that initially don't seem like medical devices but evolve to become a medical device over time. Start thinking about this now so you can be informed as your healthtech evolves.

Once you've got a sense of how your value proposition and intended purpose fit together, you should read more about the appropriate regulatory and evidence generation pathways such as clinical investigations and evidence generation plans. This will put you in better stead to have conversations with the NHS or care providers, to generate evidence and potentially pilot the technology.

Ultimately, you'll need to generate convincing evidence to prove the value proposition and meet regulatory requirements. But generating evidence can cost time and money. So, it's important to choose value claims that are realistic and feasible to demonstrate. Taking a closer look at support available for generating evidence will help you plan for later, particularly with budgeting.

Finally, data protection and research approvals can feel like barriers. That's why we developed a comprehensive overview of research and data governance requirements. Reading our data guide will help you understand all the data and research governance implications for your healthtech, across the whole of its life. You can use our data compliance checklist to help your team make sure you're following appropriate principles for using health and care data.