IQVIA TECHNOLOGIES

White Paper

Future Proofing QARA AI Practices

Adapting to AI developments in healthcare regulation.

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Introduction

AI as a tool offers many benefits to the life sciences industry but it is not without challenges. With the introduction of the EU's AI Act and the U.S. and EU signing an agreement of collaboration regarding the regulation of AI, it is imperative that QARA departments can guide their companies to adhere to associated AI requirements and standards. Since healthcare data is inherently sensitive (and high-risk), companies must be able to recognize and mitigate potential biases and risks in addition to being transparent with acceptable risks. In a recent LinkedIn Live event, ABHI Director, Regulatory and Compliance, Phil Brown; Founder of PharMedTech and Triune Technologies Ltd, Gabriel Adusei; and IQVIA Senior Director of Product and Strategy, Digital Products & Solutions Mike King, discussed the evolution of AI within the quality and regulatory arena, with a focus on patient safety, data quality and minimizing bias.

What initial education do regulators and companies need and what continued education is needed as AI tools evolve?

King: There was recently the coming together of the US FDA, Health Canada and the MHRA to issue a strategic response to some advancements in AI, particularly around machine learning. Having three global regulators agree in principle, on something as significant as AI, is a big step forward. The challenge is how that then pulls through into execution. When you consider factors such as product types, different standards, different countries, with different technical and toxicological testing requirements and clinical activities, things get complex very quickly. So the regulatory and the quality professionals not only need to learn about things that pertain to their global healthcare regulators, but also need to look at broader regulations for which the impact on healthcare is a subset of their scope., like the AI Act that we've seen in Europe, cyber security and European GDPR, all of which can have an impact on medical devices and other systems that are CE marked for the use in healthcare, and then registered globally for use in global healthcare.

Brown: You can have a fantastic system, but the regulator still needs to know how to function that AI tool to get the information they need from a particular data core to ensure the safety of patients. The regulators are really struggling with capacity, and so to have tools like AI is a fantastic opportunity. When it comes to education, one of the things that we struggle with, I think, as regulated professionals, is to fully understand the environment that we work in. There are so many allied regulations that fit around medical technology, especially now when you think of the environmental questions around REACH and hazardous chemicals (RoHS) and Waste from Electrical and Electronic Equipment (WEEE), and all the net zero questions. How you integrate all of that, from a business perspective, into technical regulation is something that AI is going to be useful for. And it's important that the regulator gets involved and understands that sort of complexity of where all those relations are because, without that, it will be almost impossible to have an effective system.

" Having three global regulators agree in principle, on something as significant as AI, is a bigstep forward."

— Mike King, IQVIA

Adusei: The UK MHRA has suggested that they will use AI tools for the initial review of technical submissions to be able to assimilate some of these regulatory requirements and whether companies are putting in the right information and addressing the issues when it comes to data handling. It is an area that is rapidly changing, and it is encouraging to see that the regulators are acknowledging this and using AI tools to help them manage capacity and enhance technical expertise.

Brown: In my experience, when you're working as a regulator, as a civil servant, you're constrained by cash quite often. We can all see the real benefits of AI: how it's going to enhance safety and the way that we work with products. But we could be working in a healthcare system in the UK, where they still use outdated Word and Windows systems on their computers. So AI, in many ways, is such a fantastic tool, but it has to be embedded in a way that it's embraced by the regulator in order to make it work properly.

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The population that needs access to medications most is older people, but they want to know what is being done with that data. These data conversations are also being had with women and minority populations — how does this knowledge affect regulators using AI or evaluating AI-powered devices? And, specifically, how does this affect QARA?

Brown: This is a really important subject. I'm going to be controversial. If you're thinking about AI as a tool for assessing safety or data. Let's pick an example, like using AI as a triage for breast cancer readings on scans – the patient is understanding what's happening there, so the patient will see that they've got a scan and that there is an AI system involved. So, there could be a skeptical barrier that the patient must get over to accept the information. If it comes to a regulatory approval, does the patient really worry too much that an AI tool is being used by the regulator? The only thing that the patient or the doctor using is the product is going to be interested in is whether that product's gone through a robust regulatory system.

Adusei: I think education cuts across the whole use of technology because there are elderly and vulnerable people who are not able to access some evolving technologies, but they need the benefits they provide. I remember that with development of finger pulse oximeters and, thankfully, the manufacturers have managed to resolve some issues with them — they would only work on certain skin tone types, all because there wasn't enough diversity in the clinical trials with a population of statistical significance to yield appropriate results from a broad demographic use of pulse oximeters. So, the effectiveness of such devices was limited to certain groups of the population. A very serious aspect of this was observed during the COVID-19 era, when pulse oximeters were giving out wrong information, and the clinicians were sending patients back home because they thought they had enough oxygen in their systems, and this could have resulted in patient deaths. It is important that even at the very beginning of design and development of any medical device with any new technology, education is put at the forefront so that people will understand if they need to get involved to help to satisfy health equity and diversity. The importance of education cannot be overemphasized. I believe the regulators are now putting into their requirements that with any submission to be reviewed they seek to find out whether enough subjects have been tested through the process, and therefore it requires education to get many people on board.

King: Quality and regulatory professionals have been reviewing documentation for quite a while. Consider the data sets that are behind some AI models: having the right volume of data, the right data structure, the right data congruence, and the right information so you can extract meaningful insights for certain patient demographics is key – not just in the design phase of a product, but also in the verification and validation piece, and even post market. Because where a product doesn't perform as expected post market, you can gather a significant amount of data using AI tools to search for things like product quality issues and potential adverse events in real world data.

Adusei: We've talked about education perhaps focusing on the wider public and the end users, but the regulators themselves need to be educated. Phil mentioned earlier that the regulators need to know they are looking for the appropriate tools they need to use to optimize the information to clear any technology or product coming onto the market. And it works both ways, not just the recruitment of subjects for clinical trial and getting the clinical efficacy across the board, but also educating the regulators on some of these emerging technologies. I think the regulators need to collaborate a bit more in terms of bringing on board research institutions and universities, and clinicians and people from a variety of backgrounds to be able to make a sound and safe decision in clearing technologies for the marketplace.

Brown: Those sort of research opportunities are real opportunities for the UK actually, because the National Health Service probably has the most diverse patient population in the world, and to be able to use that data pool using AI tools is a fantastic safety opportunity for patients – to be able to look at that diversity in a way which hasn't been used before is a brilliant way of looking at how, for example, products can be used in pediatrics, or how they can be used in different minority populations and female populations.

There are over 20 different data biases that we know of right now. So, what is the acceptable data bias risk for regulators? And what does this mean for QARA?

Adusei: Biases are inherent in the things we do, and the best approach is either identifying the bias in the first place and mitigating it or keeping it as it is and managing it so that it doesn't cause any harm. I think there is always that issue of how much data is enough to make a sound clinical decision regarding the efficacy of a medical device. When a new technology is being introduced into the medical device product, at times there isn't enough data out there so one needs to undertake clinical research or clinical evaluation to convince the regulator that it's safe. The data piece of the whole design and development and validation is critical, and it comes down to the quality of the data and how diverse your data is in order to capture every population group. It is important for manufacturers as well as the regulators to really consider data points as one of the most critical areas of bringing technologies to the marketplace.

King: I think Gabriel touched on a key thing there, particularly with the use of AI, potentially to look for data to support product development and product design activities. Wherever humans are involved, there is bias, be it the writing of the AI algorithms, the vectors that are behind the searches, the data sets that have been segregated to train the engines to do what they need to do, and/or the individuals that could be keying in and answering or asking certain questions. The key is building and operating in such a way that you can minimize those biases. Another key factor is acceptable risk. In the world of QARA, "safe" means "acceptable risk", it doesn't mean "no risk". means acceptable risk, it doesn't mean no risk. It's around having acceptable risk and products that are designed, developed, verified, and validated across the processes in such a way that there is a high level of confidence in the performance of these products. Where there are gaps in data, we could potentially use AI to crawl through some real-world evidence to support or augment the clinical activities that are underway, and with that, we can gather some science behind how the products are performing to increase the confidence that we do have something that is safe and effective, and that can be offered to market.

And conversely, from the regulator's perspective, if you imagine the volume of approvals that the regulators need to cover on the pre-market regulatory side, if they could have AI tools to help them screen the submissions, to identify where data was strong or where data was weak, that would allow the regulators to conduct focused reviews on submissions and to really engage in a professional to professional discussion, to improve the quality of the submission, and drive that confidence that products were considered safe, i.e., the risk was minimized to the point where both parties were comfortable releasing product to market. AI and data are intrinsically linked, and they can help both with the creation and the innovation of medical solutions as well as the pre-market regulator review, and the post market surveillance.

Brown: Medical device regulatory people are good at risk. We've been brought up on integrating things like risk management tools right from the beginning of a regulatory technical file. The way that Mike was describing things there is absolutely fascinating, because what it essentially means is that the regulatory decision is with the regulator, and actually in Europe at the moment, it's not with the regulator, it's with the conformity assessment body or the notified body, so AI potentially being able to give back some of that regulatory control to the regulator might actually have a fundamental effect on the way that regulatory structures are set up globally.

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>
> *— Gabriel Adusei, Triune Technologies*

Companies need to have clean data sets and successful algorithms. How will companies align with the speculation that these will need to have a level of transparency for patients? And how does QARA prepare for this?

Adusei: I think data transparency needs to start from the manufacturers, just as you declare the composition of a product for evaluation, for regulator review, and when it comes to labeling. I think — and I've advocated for this — that any technology in a device that uses AI needs to be symbolized. And I have challenged the ISO Technical Committee 210 to revise ISO 15223 to include labeling symbols and information that is to be provided by the manufacturer, to include AI symbols, whether this device contains generative AI as an element of it, or another AI tool. The information needs to be transparent enough for the end users to know that they are using the technology that is AI based or embedded.

Brown: As an industry, we are being driven more and more, quite rightly in my view, towards transparency and patient data transparency. One of the ways that you can ensure consistency, transparency, and security of the information that can come out of AI tools is to ensure that the algorithms and the mechanisms that you're using are standardized in a way that makes things appropriate for their output, which can then be judged according to, as we've said before, the relative risk of the products you're using.

There are lots of ways that data sets can be used, and aligning with that speculation for transparency and requirement for transparency is something that which is different in AI, but needs to be addressed.

What is the ABHI seeing around the uptake of AI and is there any variation between the larger corporates and the SMEs in that uptake?

Brown: I think that there are differences in the way that AI is being used. Some of our smaller members are AI based, so they're fully embracing everything that is coming their way on AI. Large companies are already using AI. When it comes to even things like technical file compilation and review and the generation of clinical evaluation work or safety update reporting, AI is already being used. With quite a lot of SMEs, their biggest headache at the moment is the general cost of regulation. With regulation changing and the requirements of regulation changing, particularly here in Europe, some of the costs, for example, auditing, have gone through the roof for them. So, the actual use of AI, which can potentially streamline some of those auditing processes, or can streamline the way that that data is being put together, I think is going to be embraced quite well by the SMEs. But everything comes at cost, so if it's available, and affordable, I think that it will be used across the board.

King: It sounds like you're saying saying the ABHI is seeing that SMEs leaning more into using AI to understand global regulations to support in optimizing things like audits and submission activity, whereas when you go to the larger corporates, they're looking for it to be more embedded throughout the end-to-end process.

Brown: A lot of the big companies work globally, so they're assessing their data on a global scale, not necessarily a local UK or Germany scale. It's on a global platform. Let's take an example of combination products — if you're using medicaments or you're on a combination product, which might not necessarily be used in one country as opposed to another, AI can hunt that all down, can give you the right way of approaching those sorts of questions. So, from a large corporate perspective, you would probably use AI in a different way than you would do as an SME.

Let's talk about the availability of AI tools on a global scale. What are some of the barriers, and how do these affect QARA?

King: Cost of tools could be a barrier. Many QARA teams are trying to do more with less in an ever increasingly complex global market, so being able to present to leadership good cost benefit for the use of the tools, either in terms of go-to-market timeline, or potentially some sort of efficiency saving, is absolutely key. But there could be those markets where that barrier to entry could be quite high, and that could then drive not just QARA teams, but commercial organizations to work closer with other commercial organizations, like the ABHI in the UK or elsewhere, to have a position of strength. The other piece is data and the importance of having the right data set of the right size to answer the right question for the right customer problem statement — where that data is absent, there will be an associated cost to go and find the data or to potentially use AI-type tools to help with that data.

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>
> *—Phil Brown, ABHI*

Adusei: I think the importance of using AI tools is becoming very clear within the MedTech space. At the start, these tools were presented as being freely available, but the premium versions, for example of ChatGPT, have some commercial interest, and therefore companies are going to be charged for their subscription to them. One needs to factor in the cost of AI tools right from the very beginning of product development, just as the technical people will think about the risk-benefit ratio right from the beginning. Of course, these things are going to cost an awful lot to use, but when you weigh that against the benefit that it will give the company, they can prove to be essential for the company to embrace and help bring safe and effective products to the marketplace.

Brown: It's important to make sure that you're using the right tool for the right job. That's where a manufacturer must do their homework to ensure the AI tool is appropriate for what they want to do, and that might incur an additional, premium cost.

Just because we can, should we use AI?

Adusei: AI tools are coming into the medical technology space quite quickly, and it is about time that the tools are embraced to do certain jobs that are quite laborious and tedious because AI can do them faster. But, as we have discussed, using the right tool for the right job to get the right data output, or the right output of it for the safe use of the device, is the most important thing. The cost is secondary. Patient safety is primary.

King: I'd say "customer centricity" is key. AI is here, and the focus needs to be on patient safety. And if you bring those three together, you'll have the right tool for the right job at the right time.

A question from the audience. How has the tone of the discussion on AI changed over the last year, specifically for QARA?

Brown: I think that it's changed quite a lot. I remember those initial discussions around using things like ChatGPT, and there was real skepticism, but it's been really embraced. And the same with all AI tools that I've encountered over the past 12 months or so – there's been a real drive towards acceptance and usage. So, I think that it has changed and it's likely to continue to change at an increasingly rapid rate. Watch this space.

Denoon: Two words excitement and acceptance! Every single client I speak to in Life Sciences (Medtech/Pharma/Biotech/Genomics) has embraced AI to some extent: a number have made astonishingly large investments and commitments.

Some of these will be lightly regulated (assistance managing existing data sets and making them more accessible; reviews of vigilance data; preparation of new claims and marketing copy; regulatory intelligence) while others will be more heavily regulated (diagnostic insights arising in the course of a Phase II clinical trial that the sponsor aims to deploy as a novel diagnostic in the Phase III trial; Novel proposed treatments using off-label medicines for third or fourth line cancer patients). QARA teams are aware of the challenges posed by initiatives like the EU AI Act, but the regulators have expressed support and indicated a willingness to work with AI/ML. This is not science fiction. This is science fact!

About the authors

MICHAEL KING
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Michael King (Mike), Senior Director of Product and Strategy at IQVIA, ensures medical device solutions meet complex global regulations. He focuses on optimizing workflows through intelligence-driven simplification and automation across Safety, Regulatory, and Quality functions. With over 16 years of experience in Regulatory Affairs and Quality Assurance, Mike excels at strategic planning, simplifying complexities, and driving operational improvements. Previously, he was the VP of International Regulatory Affairs for a Dental Technology firm. Mike holds a Physics degree from Oxford University.

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Alex Denoon heads the life sciences regulatory team at Bristows with over 25 years of experience. He holds an LLB and a BSc in Human Genetics. Alex spent over five years in-house, including as GC and Company Secretary of Biotech Australia. He advises clients on regulatory strategies throughout the lifecycle of pharmaceuticals and medical devices, focusing on complex issues such as genomics, cell therapies, 3D printing, and healthcare apps. Alex has contributed to developing various regulatory frameworks and guidelines and is widely published.

GABRIEL ADUSEI, MSC, PHD.
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Dr. Gabriel Adusei has over 33 years in the medical device industry, blending academic studies and professional roles. He has influenced global regulatory practices through numerous high-profile projects and articles. His expertise spans Quality Management Systems, Regulatory Affairs, Risk Management, Usability Engineering, Clinical Evaluation, SaMD, and more. He lectured on Dental and Orthopaedic biomaterials and worked as a Technical Reviewer and Auditor for BSI and Intertek, gaining extensive auditing experience. Dr. Adusei holds a PhD in Biomaterials Science from King's College, London, with research contributing to publications on dental and orthopaedic devices.

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Phil began his career at Smith and Nephew, qualifying as a Graduate of the Royal Society of Chemistry in 1984. He joined the Woundcare Regulatory Affairs team during the enactment of the Medical Device Directive. His career includes roles at Genzyme Biosurgery, Quintiles, Wright Medical Technology, and Kinetic Concepts Inc., involving work with novel technologies and liaising with regulatory authorities. Since June 2016, Phil has been the Director of Regulatory and Compliance at ABHI. He chairs the BSI standards working group TC/210 on Quality and Risk standardization and is a Fellow of TOPRA. working group TC/210, which covers Quality and Risk standardisation and is a Fellow of TOPRA.

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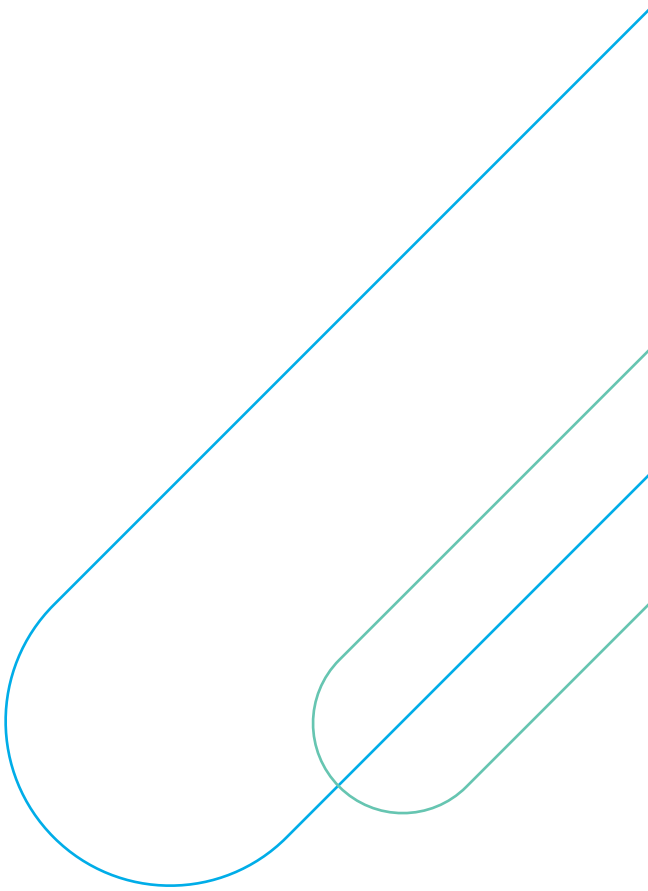

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