DIA Global Annual Meeting 2023 | Key takeaway points and thoughts on how to leverage them

By Chi Pakarinen, Programme Lead, MediPaCe

Session number and name	Key take-away messages/ learnings	My thoughts on how to use the learning and other comments
#100 Opening plenary: Revolutionizing life sciences – How diversity, innovation and AI are accelerating the future of healthcare	Make technology and science work for health to improve health systems.	The main message here was don't be afraid to learn about and test large language models like Chat-GPT.
	Accelerate innovation with the use of AI: get engaged with AI but be aware of which data it is trained on → demand and practice transparency. AI should be used as a co-pilot, not to let it lead.	
	"Diversity is the fuel of innovation, and innovation is the engine of transformation."	
#105 What's in the future for global advancements in PE and Patient-Focused Medical Products Development?	Patient engagement is making R&D more efficient and the use of patient experience data (PED) and/or patient-relevant data is becoming an essential part in regulatory evaluation, thus it's not a nice to have for pharma and medical technology companies anymore.	Learn about and train your team to understand what is considered 'patient experience data' (page 4) and how it is being used in regulatory assessment in order to be able to plan it in product development strategy.
	Regulatory guidance exists on what is considered PED, how and when to collect it and how to design for robust data collection and analysis that has higher chances of being considered in the regulatory assessment.	Download FDA's PFDD guidance series and share internally to increase capacity building.
#131 Beyond the why: How to effectively implement a patient-led approach to clinical trial design and conduct	It's time to have more integrated patient engagement where patients co-design trials and companies have a patient on their staff as subject-matter-expert to make clinical studies accessible to also those who might not afford it or have health insurance.	It's time to stop just talking about patient engagement but also show how your company is involving patients as partners throughout the drug research and development lifecycle.
	Companies should think about 1) designing clinical studies **around** patients' everyday lives, and 2) having flexibility and options built in from the start. It's not about making everything a decentralised or remote study (DCT), but about being able to offer different ways to participate.	Work with a patient partner who can work with your team to design the study protocol to increase accessibility, recruitment and retention.

#151: What Patients and Care Partners are Saying about Hybrid and Decentralized Trials	Don't assume that the solution your team created will be loved by patients, always have a dialogue to check what is the most needed by patients.	Convene an advisory meeting with relevant patients and **have an open discussion about your protocol and how attractive/ feasible it is** from the patients' perspective.
	To not create extra burden during the study. ASK: Do we need to collect this? Are we measuring what's important?	
	Have flexibility and options.	
#212 Full exposure: AI to advance, replace and add efficiency for patient benefit	Instead of doomsday thoughts, think about the immediate benefits AI and innovative technologies can produce and the good it can be used for today. It's not 100% right, but it can help empower us to do more as we learn to harness its power.	In order to fully harness the technology, all relevant stakeholders should be using it. As said in the first session: diversity is the fuel of innovation and innovation engine for transformation.
#226 Patient experience data in the label: closing the gap	It's important to include PED in the label because if it's not, we have created an unnecessary burden to patients by asking for that data in the first place.	Ask questions and measure things that are also meaningful to patients!
	There is a need to have a standardised way of using PED in regulatory and payer evaluations and payers should be given more information to help them understand the full picture (or totality of evidence) and why certain information is and isn't in the label.	Using PED in regulatory assessment is a relatively new thing and you can learn with the regulatory by interacting with them in the design phase of your product development plan. Share your plans for PED and what part it plays in your totality of evidence and hear their feedback. Work with patients to know what is meaningful to evidence.
	For EMA, there most likely won't be an all-encompassing PED checklist to be created, but rather each case will be assessed individually. There is opportunity for harmonising practices, training review staff to jointly look at PROs, patient preferences and clinical data in evaluations.	
#247 Measuring impact of PE across R&D	Measuring impact of patient engagement is hard especially in the first year to set the baseline. In addition, we'll have to understand that it whatever we are measuring, it will evolve over time as the company's strategy, KPIs and objectives change.	A number of pharmaceutical companies are creating dashboards to make insights gathered through patient engagement more actionable. Check the recently launched PALADIN initiative by Sanofi.
#257 Roundtable: Disrupting the status quo: best practices for bringing together patients and medical staff to positively impact trial diversity	How can lasting change be made if even the leadership is not diverse enough?	Diversity should show in every aspect of the business.
	There exist various resources and a community that wants to make a change for more diversity in studies. Go to where the community is to understand the barriers, to inform, train and educate, and to create pragmatic solutions.	In the US: consider collaborating with Federally Qualified Health Centers (FQHC) that provide health services to medically underserved areas and population.

#303 Returning individual data to trial participants	There are initiatives working on enabling returning of individual data back to trial participants in a timely manner and useful format so that if needed, this data can be used in the participants' own healthcare.	Resources mentioned: Patient Data Access Initiative (PDAI), MRCT's IRR case studies, IMI-FACILITATE's work, and Pfizer going live with their own data return program
#351 Real-World-Data and end-to-end patient centricity	Real-World-Data (RWD) can provide a more holistic perspective to a patient community's realities, e.g., in terms of identifying disparities in access to care, and can be used to inform and enable physicians and patients in shared decision-making improved healthcare/ treatment plans. Challenges: lack of harmonised codes, incomplete integration, sampling biases and the difficulty of mapping the complexity of individual patient journeys.	In order to gather the kind of RWD that helps you address patients' unmet medical needs, you'll need to **work with patients as your partner in designing how and what to gather and interpreting what has been gathered.** Despite challenges, opportunities exist in patient-centric generation and application of RWD.
#405 CIOMS Patient Involvement Report	This report was a multi-stakeholder, multi-country collaboration to describe the importance of patient involvement, and was published in September 2022. EMA has committed to implement the recommendations in the report.	Read and share the Patient Involvement Report that is downloadable for free from CIOMS website.
#413 Reflections from the other side of the table	Participating/ or trying to participate in clinical trials has opened these presenters' eyes to some of the challenges experienced by the patient community. I think the intention of this session was good, but it might have unintentionally painted a rosier picture of the realities and the multitude of challenges the patient community is facing with clinical trials. Left this session with mixed feelings…	

Did you find this useful? Let us know on LinkedIn, Mastodon or Twitter!