

Virtual Round Table Summary

Patient Engagement to overcome challenges in clinical development resulting from the COVID-19 outbreak

admedicum Business for Patients organised a series of small roundtables with patient and industry experts. This an anonymised summary of those conversations in order to help you with your own decision making. With the current challenges in the healthcare system, we believed it important to listen to patients, understand their concerns, and co-create strategies to lessen the impact of challenges imposed by Covid-19.

Thank you to our panelists for taking part in this knowledge exchange, we all learned a lot from each other.

admedicum is always here to support those active in clinical research with patient engagement, let's keep sharing ideas.

Aspects covered included:

- ***Problems facing patients and the industry due to Covid-19***
- ***Addressing the issues with patient engagement***
- ***Patient engagement and clinical trials***
- ***Opportunities for a truly patient-focused product development***

We are covering this content in a mini-series of four blogs.

Problems facing patients and the industry due to Covid-19

- Disruptions of regular care routines

Patient representatives taking part in the roundtables shared that their members and friends living with chronic diseases are facing disruptions to regular care routines and scheduled treatments are being cancelled or postponed at hospitals.

- Delayed or hampered access to care

Patients are having to change treatment formulations or delay the start of new treatment regimens. Patients taking immunosuppressants as part of care for conditions like cancer are in a particularly challenging situation. Not all care can currently be done over telemedicine, for example how can an MRI to check tumour growth be done virtually? One patient representative highlighted a particularly difficult situation facing the autoinflammatory disease community. A treatment used by many patients is also being examined as a possible treatment in clinical trials for Covid-19. Patients living in Italy and Spain have already highlighted issues accessing the treatment

before this started. Patients can not visit hospitals as normal to receive the treatment infusion and worry about access in the future.

- **Clinical Trials suspended or postponed**
From large pharma to small biotech, clinical trials are being suspended and postponed. Patients want and need to have access to treatments that improve their quality of life or in some cases save them. Time matters. A pause in research of at least six months means increased waiting time for patients with high unmet medical needs. Our panelists pointed out that their ATMP clinical trials that may require surgery or extended hospitalisation are being cancelled in all EU countries.

- **Fundraising jeopardized or reduced**

Researched focused patient charities can't fundraise in the new pandemic environment of growing unemployment. Even gaining access to peer reviewers and ethical review boards are becoming more challenging and affecting the pace of research. Some research charities are wary that funds that were previously pledged to their clinical programmes could be shifted in the future.

- **Hesitance of patients coming to the hospital**

In some cases patients view the hospital as unsafe due to their immune system issues and are avoiding going to the hospital even when care may still be available. We can expect that patients may drop out now or even when trials restart due to a reluctance to attend site visits. This may lead to protocol deviations and complications in the biostatistical analysis later in the year.

- **Need for support to overcome challenges**

When clinical trials return to normal in the future, site staff may not have the time to help patients in normal activities like supporting families and arranging transportation to a site. Patients and their loved ones will need more support, their concerns listened to and addressed in a way that demonstrates the value of their role in research.

- **Prolongation of IRB and regulatory approvals**

Regulators have made it clear that changes to clinical trial protocols are possible, but it takes time to get IRB approval, then to implement those procedural changes across global trial sites. By then, the situation in many countries can completely change.

- **Lack of reliable and valid information**

The patient community feeling is not very well informed and mention a lack of communication from hospitals.

Addressing the issues with patient engagement

First off, sponsors need to reach out to the patient communities where they are active and offer information (as it becomes available) and support. Sponsors have to rethink their communications activities and try to create a calming effect by looking at things from positive perspectives. There could be opportunities in this slowdown time to find cooperative projects to raise disease awareness while continuing to build trustful relationships.

Companies and researchers need to create a ***Patients Communication Plan***, which could be an ongoing document or website, for sharing information with the patient community now and when restarting trials after Covid-19. This plan could share proposed changes to clinical trials, address risks, and act as a checklist for preparation.

Patient organizations are doing truly amazing work by updating their members on Covid-19 precautions, guidelines, and ideas for mitigating the damage on webinars, dedicated webpages, and even setting up telephone help lines. In some cases, learned societies partner with patient groups to answer patients' questions and create detailed responses to continue to support patient communities. Sponsors can look for ways to support those publications or partnerships.

Patient organizations are also organising online conferences and webinars that bring together the leading companies in their disease area, scientists, researchers, and the patient community to address issues both related to Covid-19 and the future of research in the disease area. Sponsors may have more technical knowledge for digital conferences in-house or access to specialists to assist these efforts.

Both patient organizations and companies can create engaging, informative digital content to meet patients needs during this time, to continue building a sense of community, and to keep the importance of public participation in research at the top of their minds. Examples could be patient advocate interviews, podcasts, or short home-made videos.

Overall, showing appropriate empathy with patients that may be facing an above-average risk to be harmed by a Covid-19 infection, should be an essential part of patient communication these days.

Patient engagement and clinical trials

Sponsors need to engage with patients on any protocol design changes and actively communicate the change to minimize dropouts. Sponsors can push digitisation more and reduce some burden to the patients or arrange for home nursing visits.

Telemedicine platforms can be considered by the site to continue collecting data in ongoing trials and saving patients the visit to the hospital. This

opportunity could change the future of biomedical research and generate cost savings for sponsors and benefits to patients from doing trials at home.

Sponsors and sites can continue to build interest in upcoming or postponed trials through online awareness campaigns that have pre-screening and a patient companion service to communicate to patients who are interested in the trial and meet the eligibility criteria.

It's possible to minimize the slowdown in patient recruitment through informing the patient community of the situation and still maintaining trial information online. Via looking at Google Trends search behavior, we can see patient interest in finding trials and more information online about their disease remains high.

Hospitals and governments have to be clear when it is safe to restart clinical trials when more information is known. This information all needs to be available easily and prominently on official company, hospital, and public web sites.

In these times, the patient2site approach (LINK to our sub-website) is becoming even more important as patients are actively seeking options to join ongoing clinical trials but may be hesitating to see their doctor physically.

Opportunities for a truly patient-focused product development

In pain there is opportunity for growth. Beyond sharing concerns, the roundtable participants highlighted opportunities for positive change.

One main thread throughout the roundtable was:

Communication with patients digitally is key and disruptions and issues can be faced with open, transparent communications with patients. Digital formats may become even more part of the "new normal" including the dialogue between patients and industry.

Public interest and awareness in health research and online research as a whole is at an all time high due to the amount of Covid-19 trials and the urgent need to create a vaccine. We all have to capitalise in this new found interest and make sure there is follow through to where patients actually get active.

We can build support for research participation more broadly. Clinical trials will have a higher standing and public recognition on the importance of clinical research will improve.

Research and development will benefit from better communication between scientists, patients and pharma.

Despite an increased acceptance of digital formats, the value of face-to-face interactions will be valued even more "after Corona".

The current situation will foster the globalization of the patient movement as patients around the globe are now faced with similar challenges concurrently.