



Ask the Experts: how business continued through the COVID-19 pandemic



In association with Alturas Analytics, Inc.

In this feature, we interviewed key figures from pharma, CRO and academia about their experiences and opinions on the impact of COVID-19 on their businesses and key lessons learnt during the pandemic. We also investigated how virtually prepared the bioanalytical industry was, as well as how the pandemic has changed the way the bioanalytical community works and communicates together.

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What challenges did you face in outsourcing work/ continuing tests during the pandemic?

Jennifer Zimmer (Alturas Analytics)

As a CRO, we maintained continuous operation, but spread our workforce out so that fewer people were onsite at any one time. This presented some challenges with scheduling, but we adapted some of our current project management tools to allow us to appropriately schedule projects and resources. In some cases, it actually allowed us to complete critical projects more quickly, because skilled staff across departments were on site seven days a week.

Chris Smith (Elanco)

Elanco (Sydney, Australia) operations have continued and we have found our supplier network to be very robust during this time with only minor interruptions depending on the location of the lab. The only challenge noted was a slowing down of the data return in the initial periods of the pandemic. As time went on there was adaption of the companies to the situation and no delays were noted.

Jan Miotto (Metrendalytics)

Initially, more work was outsourced to CROs as pharma companies shut down or reduced their own internal lab testing capacities by restricting the number of lab personnel on site. However, CROs' lab staffing was also impacted, as scientists took time off due to concerns about contracting the virus while working at the lab or being forced to take time off since their children's daycare had been

closed down due to government mandate. This reduced CRO lab capacity resulted in delays to some projects. At the same time, projects were also delayed by pharma, due to an inability to recruit subjects for studies. Proactive client communication on project delays was key to helping ensure all stakeholders were on the same page. In the long term, until a proven vaccine becomes available, it is expected that a fraction of the workforce will not return to office full time. Companies will therefore need to embrace shift hours and new considerations for space utilization.

The collaborative research team of Dr Kamal Dua (University of Technology Sydney)

One of the biggest challenges was the lockdown and closure of several research service provider companies where our work was outsourced for testing. Since our collaborators are based at locations across the globe, suspension of courier services hampered sending samples for testing to our collaborators labs as well.

How did your company ensure effective communication?

Jennifer Zimmer (Alturas Analytics)

We implemented or expanded the use of multiple online communication platforms, such as Zoom and Teams, in order for communication among staff and collaborations with sponsors working remotely to continue uninterrupted. We also increased our internet bandwidth and acquired additional VPN authentication devices.

Relevant security and compliance policies were updated and SOPs revised as applicable. Our IT and Quality Assurance Units introduced the ability to conduct virtual audits. Additional wireless hotspots were installed throughout the operation in order to accommodate interactive facility tours.

Chris Smith (Elanco)

Well-structured meetings were even more key than normal. As 90% of my work is normally conducted over the net this was not a problem and in the modern world the infrastructure in the main handled the extra strain. Home working was managed by my company in making sure my home office was as good of an environment to work in as my site office.

Jan Miotto (Metrendalytics)

Most CROs used typical tools for meetings and communication, such as Microsoft Outlook meetings and email, Microsoft Teams and even text messaging. The pandemic forced many labs to really make better use of these tools, which required more disciplined and consistent use by all stakeholders. Other, less used, tools – such as virtual private networks – were expanded to allow for off-site access by individuals and teams using other systems, including eNotebook and Watson LIMS. Cloud-based systems, such as Salesforce, NetSuite and ZenQMS, as well as Metrendalytics' business platform, continued with 'business as usual', as these were already well adapted for virtual usage.

Suranga Senanayake (University of Limerick)

Just as many other institutions, ours as an academic university ramped up the use of virtual conferencing to stay connected [1].

However, of relevance to healthcare trainees, we have been challenged to find means of achieving 'hands-on' experience. Whilst not a complete replacement, one surrogate we are actively pursuing is e-health applications, such as virtual doctor-patient encounters. We believe virtual simulation of such clinical encounters will be an important supplement in case of future lockdowns.

The collaborative research team of Dr Kamal Dua (University of Technology Sydney)

We were impressed by the IT services of our university, which ensured effective communication and virtual meetings to be achieved and conducted, be they teaching related or research. Platforms such as Skype for business, Microsoft Teams and Blackboard Learn were very useful.

What measures have you introduced to minimize the potential spread of COVID-19 in a laboratory during the pandemic?

Jennifer Zimmer (Alturas Analytics)

Alturas encourages staff to stagger their work schedules and utilize weekends. All personnel who could perform their work from home were set up with everything they needed to efficiently do their jobs remotely. We moved people around onsite as well, in order to decrease the number of people in shared spaces. Masks are required in all shared spaces, and temperature monitoring and additional deep cleaning takes place daily. We moved people around onsite as well, in order

to decrease the number of people in shared spaces. Masks are required in all shared spaces, and temperature monitoring and additional deep cleaning takes place daily. We have placed hand sanitizer everywhere in the building. Furthermore, if an employee has traveled they are required to self-isolate before returning to the facility.

Chris Smith (Elanco)

This has been a successful implementation within my lab team. The lab week was extended to 7 days and we programed in time when people can work in the different areas ensuring space was maintained. This was found to be popular as it allowed for flexibility with caring duties at home with children. We also implemented and maintained an on-site policy of group separation in shared areas enabling separation from other groups aiding in tracking if required.

Jan Miotto (Metrendalytics)

Most CROs first re-emphasized basic safety requirements regarding proper personal protective equipment such as gloves, lab coats and eyewear in lab areas. In addition, lab staff were reminded that all human and monkey biomatrices should be treated as infectious and must always be handled in biohoods. Social distancing guidelines and other CDC recommendations were also provided, enhanced, repeated and daily cleaning of common areas was implemented. Special bonuses are also increasingly being given to on-site personnel in recognition of their special efforts and dedication during the pandemic.

Further, most CROs determined for which staff it was considered 'essential' to work on

site and which could work remotely. The remote staff were provided with appropriate hardware and software to enable remote working. Depending on availability of lab space to maintain social distance, essential lab staff were put on different types of shifts, such as an early-week and a late-week shift covering the full 7 days of the week. Use of dynamic scheduling tools for both scientists and instruments is critical for ensuring each laboratory is measured in its approach to minimizing the number of personnel on-site at a given time, whilst also allowing enough time between shifts for sanitizing equipment and work areas. Many laboratories are now implementing the 'new normal' for buildings, which includes personnel temperature screening, monitoring the quality of indoor air, deployment of UV technology, adoption of touchless activations in all common areas, queuing lines for elevators and deploying sanitizing stations throughout.

Suranga Senanayake (University of Limerick)

I think the term 'social distancing' may have been overused somewhat. 'Physical distancing' will have to become the norm until an alternative preventive/treatment strategy is available. We have introduced the 2-meter distance rule within our clinical laboratory and educational spaces. However, now more than ever, we need to remain 'socially closer'; humans are, after all, critically social beings. Scientific endeavors will not last without collaboration.

The collaborative research team of Dr Kamal Dua (University of Technology Sydney)

During the earlier stages of the pandemic, all research in our laboratory was suspended. Recently, our labs have reopened with limited

capacity, with the introduction of one-way systems and the use of face masks/face shields in our research facilities.

What lessons have you learnt in terms of infrastructure preparation, planning and testing?

Jennifer Zimmer (Alturas Analytics)

Our disaster recovery plan, which we never thought we would need to implement, held up under pressure. Earlier this year, before COVID-19 was declared a national pandemic, Alturas conducted a mock disaster based on this scenario and identified potential responses, which we ultimately implemented. Twice weekly meetings of the department heads were initiated to ensure that the lines of communication stayed open. We have cut back somewhat now that we have a few months under our belt, but those initial meetings were very important to establish protocols and make sure that ongoing communication went smoothly.

Chris Smith (Elanco)

Planning has been key but our infrastructure has not changed.

Jan Miotto (Metrendalytics)

Most CROs feel there were two key learnings. First, labs need to be able to have access to information technology to manage operations and processes remotely. Everyone needs to be well versed and comfortable using this technology; use of spreadsheets or non-database sources were problematic for real-time sharing of information. Second, it is imperative that on-site, essential lab

personnel adhere to both basic safety requirements and pandemic-related items, such as social distancing. Determining available lab space has been key to ensuring this has been achieved. Acting on these learnings will only become more important depending on how long this pandemic lasts and will aid proactive preparedness for the next one. Having a good understanding of how much work is taking place digitally will accelerate technology-enabled remote work. At Metrendalytics (NJ, USA), we have always recognized the value of an online work situation and had the infrastructure in place to do so. As a result, our operations have not skipped a beat during these times.

Suranga Senanayake (University of Limerick)

From our experience, we expect high-fidelity simulation technology to play an increasing role, particularly in the training of healthcare professionals. Modification of traditional education and training spaces is necessary to achieve a simulation-ready environment going forward.

The collaborative research team of Dr Kamal Dua (University of Technology Sydney)

One key lesson we have learnt: always have a contingency plan for research-related activities. Infrastructure needs to be designed that allows for effective social distancing in case of future infection outbreaks.

Are there any technologies that you have used to ensure that work continued efficiently?

Jennifer Zimmer (Alturas Analytics)

We were able to adapt our project management software to allow us to track the personnel who are available onsite versus offsite. This system also provides accessibility to current project metrics including status, laboratory activities, batch runs, invoices and contracts in real-time. It also provides prudent resource management based on the available real-time data. Using online meeting tools, such as Zoom, has allowed us to maintain personal service for our sponsors, provide virtual audits and have face-to-face internal meetings. There are so many good collaboration tools available these days, which has certainly helped to keep us working at full capacity.

Chris Smith (Elanco)

Business as usual except for a strong IT use for presentation of data and meetings with different project groups.

Jan Miotto (Metrendalytics)

Despite the significant investment that pharma has made in technology, the primary problem still facing the scientist today concerns finding data when they need them. Historically, technology has focused on replacing existing paper processes with electronic counterparts. We must ask ourselves, are we going to continue to build tools to support existing business models and ways of working or should we begin to think

about tools to reinvent the ways we do business? Tools that enable a flexible business model, are cost effective and allow for remote access will be in high demand moving forward. These will allow us to progress beyond just managing data, to begin doing interesting things with those data. Labs using the Metrendalytics bioanalytical lab and business management software have been able to remotely manage all aspects of operations from proposal to award, project management and scheduling/monitoring of key deliverables to invoicing, revenue projection and tracking. The system integrates information from other stand-alone software systems – including Watson LIMS, Salesforce, StudyDoc and NetSuite – and leverages this to fully manage the entire bioanalytical process, project management, scheduling and milestones. The system also features multiple modules for specific processes, such as proposals, sample management, lab, QC, QA, project management and finance. There are multiple electronic lab notebook modules for specific lab processes, including reference materials, critical reagents, instruments and equipment.

Suranga Senanayake (University of Limerick)

E-conferences and e-learning are the obvious in this regard, which we have heavily relied on to maintain lines of communication and education. This is consistent with nearly half of surveyed scientists indicating their intra-team communication has not dipped, with one-fifth of respondents even experiencing an increase according to a recent report [1].

The collaborative research team of Dr Kamal Dua (University of Technology Sydney) Blackboard Learn was one of the key technologies we used to ensure effective teaching without compromising on the quality of teaching. Regarding research, all wet lab work was suspended, however, we used the time to write up and publish previous research.

It is reported that the way we work will never be the same again, do you agree?

Jennifer Zimmer (Alturas Analytics)

Some of the communication platforms that we implemented at the beginning of the pandemic to allow for increased offsite work have actually helped to make us to be more efficient. We would not have invested the time or resources in these platforms had it not been for this pandemic. Also, we have become quite proficient at hosting virtual audits. We have successfully hosted multiple remote client audits using Zoom and document sharing including electronic reviews of chromatograms, as well as LIMS and electronic lab notebook data. One of the first virtual audits included a three-week FDA regulatory inspection. I don't think that these audits will be going away anytime soon. Even when normal travel resumes, these audits are a cost-efficient way for sponsors to qualify laboratories.

Chris Smith (Elanco)

I think our communication skills have improved for sure and I have noticed a more flexible approach to myself working in the southern hemisphere with more willingness

to take calls at different times. This means that the nine to five timings have been relaxed to allow flexibility across the board.

Jan Miotto (Metrendalytics)

I absolutely agree. The coronavirus pandemic was – and is – a world-changing event that has touched the lives of everyone on the planet. On a positive note, it has served as an accelerant of technology adoption and innovation. Companies that can do it better, faster, cheaper, more efficiently and adopt more creative approaches to problem solving will leapfrog to the forefront of the industry. We will see more of a focus on developing technologies that can deliver transparent, secure and reliable data sharing. Labs have learnt that we can – and must – work remotely on many tasks without significant impacts on performance. Technologies that have facilitated our ability to do this have been brought to the forefront in lieu of more typical investments in people and instruments. Everyone has learnt to be more comfortable using the technologies and tools necessary for working together effectively under these conditions. At the same time, we have learnt that labs can reduce their fixed costs on building office space by giving folks who can work remotely the tools and training to do so. The upside is improved quality of life for staff who can significantly reduce commute time, stress and costs. Time gained can be reinvested into actual work for clients and conducting more science. While the 'new normal' is still unfolding, it is becoming increasingly clear that the future will be anything but normal. It is always important to remember that during these times of disruption, uncertainty and challenge, those

who can reinvent themselves and move forward will open a gateway to an abundance of opportunities.

Chris Smith (Elanco)

I think our communication skills have improved for sure and I have noticed a more flexible approach to myself working in the southern hemisphere with more willingness

Suranga Senanayake (University of Limerick)

Three words come to my mind: flexibility, adaptability and pivotability. These may prove to be key attributes for all scientists, particularly younger trainees in more precarious situations. As reported in a recent international survey, 66% of respondents used their extra time from lockdowns due to the pandemic for career development. Further, an impressive >90% of life scientists utilized virtual conferencing to foster collaborations [1]. So yes; I agree that our patterns of work have drastically changed, in some respects, for the better.

The collaborative research team of Dr Kamal Dua (University of Technology Sydney)

We would absolutely agree that the way we work and communicate will never be the same again. One of the most positive effects of the pandemic has been that we have learnt that physical distance is not a barrier to effective work and communication – these can be achieved and maintained virtually.

References:

1. Korb J, Stegle O. Effects of the COVID-19 pandemic on life scientists. *Genome Biol.* 21, 113 (2020).

Meet the experts



Jennifer Zimmer is the Laboratory Director at Alturas Analytics, Inc. (ID, USA) and has been working in the field of bioanalysis for over 20 years. She received her BA degree in English and Zoology from the University of Idaho (ID, USA) and her PhD in Pharmacology from the University of Colorado Health Sciences Center (CO, USA), working in Dr Robert Murphy's laboratory on the leukotriene lipid mediator pathway. Her post-doctoral experience in Dr Richard Smith's laboratory focused on using metabolomics to elucidate disease pathways and to discover novel biomarker targets.



Chris Smith has been in the bioanalytical field for over 25 years working for various pharma companies and is currently located in Sydney, Australia working at Elanco Animal Healthcare in the role of Director of Bioanalytics. The animal health care business was a new role for Chris as he has spent majority of his time in the human pharma working in clinical and preclinical environments with small molecules.



Jahanara (Jan) Miotto is President at Metrendalytics LLC (NJ, USA), which helps organizations transform their business into data driven and analytic focused organizations to realize significant increases in efficiencies and profitability. Backed by decades of experience in pharmaceutical research and laboratory operations, Metrendalytics fills a critical market need for customized software tools that easily integrate with existing systems, have remote access and enable CRO's and sponsors to be more effective and strategic with their data.



Suranga Senanayake is a faculty member of the Graduate Entry Medical School at the University of Limerick (Republic of Ireland). Senanayake currently serves as a Clinical Tutor and Simulation Coordinator in Medicine and Surgery at Midlands Regional Hospital Tullamore (County Offaly, Republic of Ireland), with a particular focus on the use of novel simulation technology.



The collaborative research team comprises of **Dr Kamal Dua** (University of Technology Sydney, Australia); **Dr Murtaza Tambuwala & Prof Paul A. McCarron** (Ulster University, UK); **Dr Dinesh K Chellappan** (International Medical University, Malaysia); and **Dr Gaurav Gupta** (Suresh Gyan Vihar University, India).