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Lessons Learned in the Rush for a Vaccine and the Effects on Language Translation

Creating and Adapting Technologies

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The rush to a vaccine has accelerated an already dynamic research process. This has led to many innovations and an evolution of procedures. The language translation industry has seen enormous stressors and has had to create and modify processes and technologies similarly.

The pandemic has changed society profoundly. The disruption in human and business interactions have not only affected the travel, conference, and hospitality industries but has also changed the clinical research landscape forever.

With the rush for vaccines, we are seeing pharmas and biotechs perform virtual clinical trials, Real World Evidence (RWE), patient visits, study enrollment, and clinical outcome assessments (COAs) almost exclusively virtually. This has accelerated the adoption of electronic patient data capture; both self- and clinician-reported. The rapidity of study startup and necessary documentation required has made clinical services companies address their models and create new technologies to meet the new normal.

Effect on Personal Lives

The COVID-19 pandemic effects have fundamentally changed our professional and personal lives, if not forever then for the foreseeable future. National lockdowns have had a significant effect on people socially and have had a knock-on effect on their mental health.

During late June, 40% of U.S. adults reported struggling with mental health or substance use.*

ANXIETY/DEPRESSION SYMPTOMS

31%

STARTED OR INCREASED SUBSTANCE USE

13%

TRAUMA/STRESSOR-RELATED DISORDER SYMPTOMS

26%

SERIOUSLY CONSIDERED SUICIDE[1]

11%

* Based on a survey of U.S. adults aged 18 years during June 24-30, 2020
[1] In the 30 days prior to survey

Source: CDC.GOV | bit.ly/dailylifecoping

A CDC survey from late June of 2020 indicated substantial reports of anxiety and depression; there is also anecdotal evidence of increased domestic violence. While only 11% of adults surveyed reported suicide ideation, 40% reported some mental health struggle.

An obvious segment of the population to also suffer is the older/geriatric population. Increased isolation documented in geriatric populations coincided with a decline in mental health, but a less well-documented source of mental hardship is occurring in younger populations having to watch their grandparents' health decline without the normal emotional support afforded them in what might be their final days.

School children have endured a seismic shift in their everyday school life. They have to not only wear facemasks eight hours daily, but also access classwork via a screen without the social interaction of their peers, which is critical in the development of social skills at a young age.

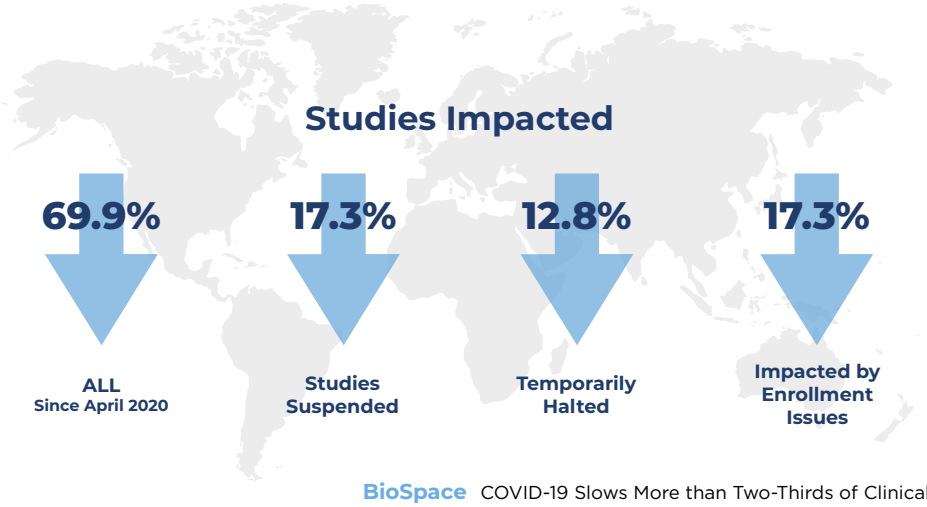
Parents and caregivers have become multitasking educators and home-working champions, juggling reading and mathematics with conference calls and email. Unexpected "visitors" during video conference calls have become a refreshing break from the stress of working from home.

Effect on Life Sciences

In the life sciences world, front line clinicians are under unfathomable stress, and while we constantly applaud them, it always seems too little. Their sacrifice is a debt we will have to repay.

Large pharmaceutical and biotech companies have stepped up to develop a vaccine, to the point of shifting resources and studies to the sole goal of finding a cure (see figure 1). Study participation and recruitment dropped last year, and many studies were put on hold with one objective in mind: developing an effective vaccine.

COVID-19 TA Global Impact



BioSpace COVID-19 Slows More than Two-Thirds of Clinical Trials, Report Shows

Most Resources Have Been Deployed to Vaccine Development

A total of 639 global industry-sponsored clinical trials for COVID-19 have been announced since early 2020, and 490 of those now have a documented start date. Of the trials that have started, 91 have a current status of "completed," with results reported publicly for 28 of the 91 (31%) but not reported for 63 (69%). We hope to see more of these studies move into the "results reported" category, as shared results will continue to move the overall field of knowledge of COVID-19 forward.

WCG Knowledge Space ™

Progress Tracker: Global Industry-Sponsored COVID-19 Trials

Data as of 1/27/2021

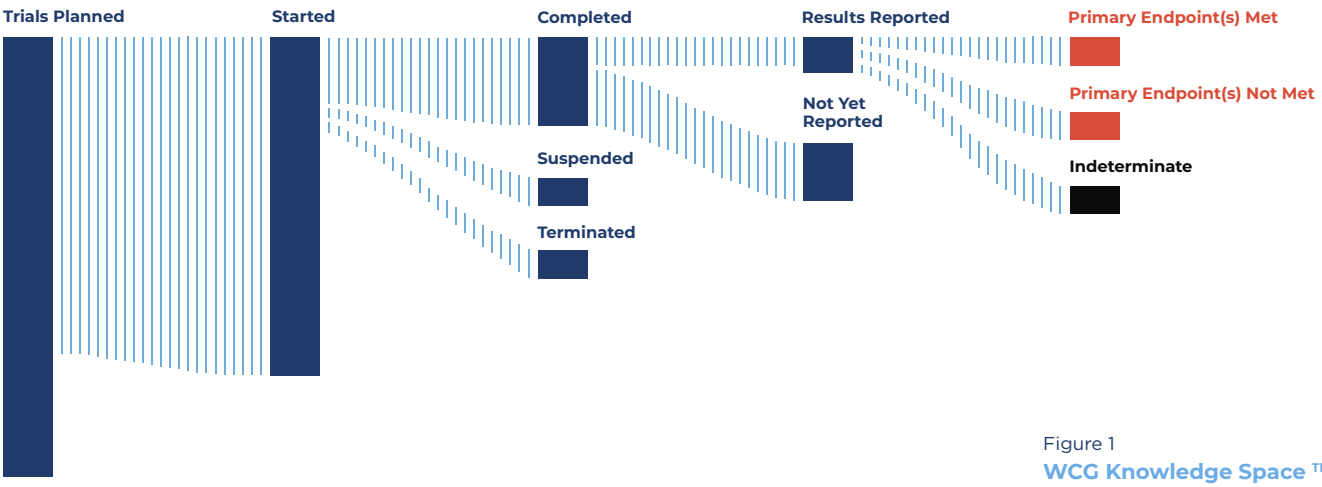


Figure 1

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Effects on Research

The explosion of research papers solely dedicated to COVID-19 was unprecedented. A study published in Scientometrics estimated that 48% of unique published articles indexed on Web of Science and Scopus between January 1–June 30, 2020, were COVID-19 research related.

Most of this research originated from the US, Italy, and China, and much of it needed to be translated rapidly to share with other global researchers. The documentation required to run these vaccine studies is defined (ICF, Dossier, patient measures, etc.) and all of that documentation also needed to be translated into multiple languages.

Pharma companies also pushed the EU to relax the translation rules for the COVID-19 vaccine—currently companies must translate the documents in all 24 EU languages. To date, no ruling on this issue has been binding. This was borne out in a September 2020 TV interview by the BEUC director stating speed should never be at the expense of safety.

Effects on the Translation Industry

COVID-19 changed the face of many businesses and the translation industry was one of them—vendors, linguists, translators, and interpreters were all a part of this big change. The rush for multilingual support for trials, need for remote interpreters, and reliance on multilingual technology were some of the challenges faced by LSPs.

Document Translation – Research, Treatments, and Trials

Under normal circumstances, most language service providers (LSPs) receive sufficient time to render and translate documents for research, treatments, and trials. However, this pandemic was not a typical race-to-market scenario, and vaccine trials are by nature different and more dynamic than other clinical trials, so the lead-time was at a premium. The strain on the translators and translation suppliers was enormous—LSPs were translating vaccine-related documents with shorter turnaround times while maintaining high quality.

Remote Interpretation

With travel bans and lockdowns, face-to-face interpreters were hit the hardest. However, virtual interpretation was required in a never-seen-before quantity. Remote interpretation saw a big uptick as companies who typically rely on on-site interpreting started experimenting with technology to support both the studies and the education of the patient population.

Effects on Multilingual-Capable Technology

The translation world experienced two dramatic technological changes because of the pandemic, with the first related to translation memories and the second to electronic data capture. While it is true machine translation (MT) was used readily, that was to be expected, but the others were not.

While many pharma and biotech companies collaborated in the research of a vaccine, which we have seen before in developing new compounds, this level of cooperation was deeper. Pharma opening their manufacturing facilities to cover the shortfall in supply was surprising and welcome.

Translation Memories (TMs) and Glossaries

In the translation industry, there was a welcome new collaboration: that of translation memories (TMs), glossaries, and style guides being centralized by one LSP and used by many. TransPerfect was at the forefront of this change with its GlobalLink technology. The centralized TM and glossary tool allowed multiple LSPs to leverage language assets while still delivering a quality translation for the sponsor with verbiage already agreed upon.

AI and Clinical Outcome Assessments (COA)

AI is potentially the most powerful tool of the 21st century and companies have been trying to harness this power in clinical trials. AI represents, for clinical outcome assessments, a fundamental change in translation process that reduces timelines to delivery while not introducing a risk for error and while protecting the integrity of the measure used. Previously, the step in moving from paper to electronic modality was almost exclusively done by human operator, but it required multiple rounds of review before final screen lock could be achieved. AI reduces the amount of rounds of review while reducing the risk profile for human error—another positive result of COVID-19.

Electronic Clinical Outcome Assessments (eCOA)

Prior to the pandemic, patients were able to attend site visits for screening and enrollment. Clinician-led questionnaires were routinely performed on site. However, the pandemic changed all of that. Self-assessed enrollment and self-assessment became more relevant than ever. Before 2020, around 50% of studies were carried out using an electronic modality (eCOA). It is now reported that 68% of studies captured patient data electronically, and in two years that

number is expected to climb to 84% (ISR Reports: EDC and eCOA ePRO Market Dynamics and Service Provider). This represents a steeper growth curve than ever seen before. The reasons are clear in that patients, especially those with compromised immune systems, are reluctant to go to hospitals in person. The social shift in working from home and home schooling has led to a reliance on screens, which has broken down barriers and allowed for broader adoption. A large portion of the population is working from home and those with children have become very proficient at logging a child into their classes while scheduling conference calls. Video calls are the standard now, which will break down the barrier to teledoc solutions in the future.

Conclusion

While the pandemic has unleashed on the world never-before-seen challenges, it's worth noting the positive outcomes as well. Large pharma and biotech companies have collaborated to develop a vaccine in record-breaking time without sacrificing any of the safety protocols prescribed by the notifying bodies. Life science technology vendors have seen a paradigm shift in the adoption of patient data gathered electronically. There is an increased demand for app-based solutions, and those deployed solutions have been updated at a faster rate than ever before seen.

LSPs used GlobalLink to leverage centralized TMs and glossaries from TransPerfect as one source, which, while not unheard of previously, was more easily adopted and was beneficial to both LSPs and sponsors alike.

While we have lost some human interaction during this pandemic, we have gained so much in terms of what can be achieved and what humans can endure. Language, and language translation, has and will always be, the fundamental building block that facilitates multi-geographical, multilingual global studies and, in times like these, it continues to do its part.

Want to learn more?
Contact us at **lifesciences@transperfect.com**.

Mark P. Wade holds the position of Global Practice Leader, Subject matter expert for COA at Transperfect Life Sciences—the largest language translation company globally. Mr. Wade's 20 years in life sciences include serving as International Regional Director for EMEA at Ethicon and Ethicon Endo Surgery, a Johnson & Johnson company. He is a published expert in electronic clinical outcomes assessments (eCOA), including two e-books, clinical posters, and numerous articles in trade journals.