

Going the extra mile to keep clinical trials on track during the COVID-19 pandemic ^[1]

People and Culture ^[2]

Sofia* has breast cancer. Each month she travels from her home in Eastern Europe to a hospital in northern Italy to participate in a clinical trial. Traveling such distances for a clinical trial is uncommon, but Sofia was eager to participate in this particular trial for her condition.

But everything changed when the coronavirus (COVID-19) took hold on the continent. With transport links rapidly shutting down due to the pandemic, Sofia was no longer able to make the trip to Italy. With only two weeks' worth of medication remaining and very little prospect of being able to obtain any more, it appeared that her hopes of receiving a potentially life-changing investigational treatment as part of a trial were over.

"We knew we had to try everything possible to get the investigational treatment to her because stopping could potentially have negative consequences for her health," says Elena Ravasi, Clinical Study Manager Group Head at Novartis Italy. Ravasi and other Novartis employees have been working tirelessly to keep hundreds of clinical trials around the world running for patients during the pandemic. They are finding creative ways to problem solve and use technology to keep operations on track.

"We tried to set Sofia up on the same trial in another nearby country, but the paperwork would have taken many weeks," says Ravasi. "In the end, with all other options exhausted, we concluded that we had to try to courier the medication to her, even with all the challenges at the borders."



Elena Ravasi, Clinical Study Manager Group Head at Novartis Italy

With borders shutting down across Europe and visitors from other countries – particularly Italy – often placed into quarantine, it became a major diplomatic undertaking for Ravasi and her team to secure the courier's passage from Italy through multiple countries to Sofia. With border-crossing permissions secured from the embassies in each country, as well as a foreign affairs ministry, the courier finally arrived to deliver the medication safely to the patient's home, enabling her to continue her treatment and securing her future participation in the trial.

Extraordinary measures in extraordinary times

It is a story that illustrates the incredible measures required to maintain continuity in exceptional circumstances like these. Novartis teams are determined to find ways for patients to continue with trials safely. There are many thousands of patients – including Sofia – who are currently participating in trials and relying on their continuation.

Clinical trials are critical for determining if an investigational drug is safe and effective. New medicines with transformative potential cannot reach patients without them.

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The manufacturing and supply chain for each one of the hundreds of global trials Novartis manages requires coordination across a complex network of moving pieces. This includes the production of investigational medicines, the distribution of these compounds, clinical site visits by trial monitors, and careful monitoring of patients for safety and efficacy. Keeping trials going while so much of the world is in lockdown and with healthcare facilities under pressure

to treat people with COVID-19 infections is challenging.

One of the ways Novartis is able to keep operations moving is by using its SENSE operations center in Basel – essentially a state-of-the-art control tower from which Novartis teams can view live data from more than 500 trials involving more than 45 serious diseases in over 70 countries – to track progress, interruptions and delays, and proactively find solutions where needed. These solutions may include remote working, moving key activities online, delivering medications to patients’ homes, and closely assessing each clinical site to ensure that it has safety measures in place before patients enter to take or collect investigational medicines.

Creativity in combination with technology will help Novartis to navigate through this difficult period and maintain continuity of its trials. The goal is to continue to deliver treatments for life-threatening diseases to patients.

Patients like Sofia.

“Sofia sent a message to her oncologist to say how happy and grateful she was for all the efforts that went into delivering the investigational treatment to her,” says Ravasi. “That meant a lot to us and we are very happy to have been able to help. We are living in extraordinary times. When it comes to patients, we have to do whatever it takes.”

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*Name changed to protect confidentiality

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