



## Ancillare in Action: Fast Track Clinical Labeling

### Issue:

A medium sized biotechnology company was launching a clinical trial to test a new compound. The protocol specifications included supplying global clinical sites with materials including the EU, Australia, Russia and nine South American country locations. However, there were major problems five days before trial launch and the company needed quick, accurate results. Country specific labels were printed incorrectly, a key clinical study manager had left the company and products were stalled in a warehouse awaiting a solution. The company turned to Ancillare to develop a solution to their supply chain challenges.

### The Ancillare Solution:

Ancillare needed to develop new labels for each country as soon as possible so the study could be started and successfully completed so that the schedule and company revenues would not be severely damaged. However, each country had independent country specific (information, format, and language) guidelines and requirements and each utilized and referenced EU/EC and WHO Annex 13 label guidances.

- Ancillare immediately responded and assigned dedicated technical regulatory compliance resources to work with and collaborate with the new client study manager and the study team
- The Ancillare team researched individual study country label requirements and integrated specific study country language, EU/EC/WHO Annex 13 guidances into an acceptable study country label.
- Ancillare developed and validated the new labels with the targeted study country regulatory compliance authority including study country government agencies located at the United Nations
- Ancillare assisted the client in printing the new labels and clearing products for global shipment

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### Results:

- Ancillare was able to complete this assignment in 4 days with the client study team.
- Newly developed Ancillare labels were shipped to clinical materials holding areas where they were applied, shipped to study target country, accepted, and distributed to clinical study sites with minimum schedule or financial impact
- The protocol was launched on-time and all investigator sites were supplied with materials needed to complete the study