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Mid-Sized CROs Consolidate in Specialized Therapeutic Areas

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Mergers and acquisitions in the CRO space are a common trend with large enterprises. However, consolidation is now moving towards mid-sized CROs through strategic acquisitions in specific disease indications. Synteract recently merged with Cu-Tech in order to expand its global footprint in dermatology clinical trials, and develop an operational infrastructure that allows them to better handle operating big pharma clinical trials in the dermatology indication. In this interview, Kathleen (Kit) Ashenfelter, VP of Dermatology Development, and Trisha Vonder Reith, Executive Director of Marketing Communications at Synteract, discuss the Cu-Tech acquisition.

MA: What prompted the acquisition of Cu-Tech by Synteract and what does this acquisition mean for biopharma companies?

Trisha Vonder Reith: Synteract recently announced the creation of therapeutic centers of development that are focused on some of the more progressive complex areas of the biopharma industry. In continuing to deliver on the strategy of developing these highly-expert therapeutic areas, we recognized our strength in dermatology and looked for a partner that had complementary collective expertise. We established a relationship with Cu-Tech as a recognized leader in dermatology; Cu-Tech's decades of experience in this area augments Synteract's considerable dermatology expertise. It's a powerful combination that makes the combined company a leader in dermatology clinical trials management.

We are very excited about what this offers to both Synteract's and Cu-Tech's combined customer base. Cu-Tech has an incredible track record of dermatological expertise and over the years has developed some incredible relationships with sites, investigators and thought leaders in the dermatology

space. Cu-Tech's team can now offer the ability to provide clinical operations, project management, and regulatory expertise as a full service with our biometrics, safety management, medical affairs, regulatory strategy and other services.

Cu-Tech has managed more than 130 dermatology studies and Synteract has managed about 120 dermatology studies. This makes the combination a real powerhouse and offers customers breadth and depth of expertise in dermatology.

MA: What are leading challenges with dermatology clinical trials?

Kit Ashenfelter: Dermatology is unique from other therapeutic areas because efficacy endpoint assessments are qualitative and subjective in many cases. They are observed visually by the investigator's trained eye versus mostly quantitative results in other therapeutic indications. It becomes really important to train the dermatology investigators to make sure that they are assessing particularly the primary efficacy parameters in a consistent manner. In several dermatological indications that require treatments with topical products, the placebo effect often narrows the efficacy range between active and placebo. Thus, it is critical to the study's endpoints that investigators' training discern differences in improvement through validated rating scales. The challenge is in ensuring that there is rater consistency across participating investigators in a study, particularly in Phase III, when the drug should be showing distinctive efficacy results in such narrow efficacy ranges. In order to mitigate these risks at Synteract, we ensure investigators are appropriately trained, for some indications pass a test, and are within consensus with their peers on the expectation on how they are rating the disease.

MA: How are clinical trials for dermatology evolving? What are some trends in this space?

KA: A trend that we are recently observing is that more sponsors are developing interest in patient-centric assessments, such as patient reported outcomes or questionnaires to support efficacy endpoints. This approach takes into consideration the subjects' perspectives on how they feel they are responding and their satisfaction level with the investigational product. These patient questionnaires are not usually selected to support primary endpoints, but rather to demonstrate improvement of quality of life. There are a few indications, such as pruritus [severe itching, a symptom of many conditions] when patient questionnaires are used to support primary endpoints. Many of these questionnaires used to be paper-based, however, we are seeing a lot of questionnaires moving towards electronic devices. Currently, in most dermatology indications, the investigator global assessment is still the most common method used to support primary endpoints; but, validated patient questionnaires are becoming very common.

MA: What about working with networks and organizations in this space?

KA: The dermatology therapeutic area is a very unique community. Investigators and their site personnel involved in clinical trials know and respect one another, and there is a close personal collaboration between the sites, CRO and the study sponsors. Many of our dermatology sites tend to be freestanding private clinics and are now increasingly becoming a part of SMOs (site management organizations). We are also working with key opinion leaders who tend to be affiliated with institutional and academic settings. It is important for us to foster a productive relationship with our sites in order to sustain performance, such as ensuring GCP compliance and producing high quality data. We believe our personal relationship with our sites is most critical to our success as a CRO managing our sponsors' trials. Through these long-term site relationships, we are developing more collaborative opportunities resulting in improving our ability to successfully enroll and complete studies within the timelines.

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