To be most successful, dermatology clinical trials should be accessible to a diverse array of qualified patients and designed to encourage patient participation. These trials should also reduce the patient and investigator site burdens, reduce start-up and enrollment timelines, and ensure consistent, high-quality assessments and data collection. With extensive experience in dermatology trials; an international network of sites with dermatology experience in key indications, such as psoriasis and atopic dermatitis; access to a large database of potential trial participants; and a commitment to tailored trial design and leveraging digital tools, PPD is ideally positioned to help sponsors rapidly and successful complete dermatology studies, even in the face of challenges posed by the COVID-19 pandemic.

ACTIVE CLINICAL SPACE
While advances have been made in dermatological medicine, including the development of novel biologic drugs, unmet needs remain in most non-malignant dermatological conditions, including acne, atopic dermatitis, psoriasis, rosacea, alopecia, and skin rejuvenation (wrinkle revision with dermal fillers or botulinum toxin products).

Widely available over-the-counter (OTC) and prescription topical corticosteroids are generally first-line treatments for psoriasis and atopic dermatitis, but they are not long-term solutions owing to issues with side effects. Similarly, biologic products are expensive and not always included in health insurance formularies, and there are variable country-level guidelines and approvals of different products.

In addition to more traditional topical products and novel injectables, drug companies are also developing oral medications. There is also significant development activity in biosimilar products for the treatment of...
psoriasis and atopic dermatitis and growing interest in plant-based/botanical type products, including those based on cannabidiol (CBD).

The dermatology development landscape can be further segmented into consumer health care (CHC) and prescription market segments, the latter of which includes topical preparations of various types, as well as oral and injectable therapies, including non-biologic anti-inflammatory agents, biologics, and biosimilars. As the number of significant treatments for dermatology continues to increase, with a number of biologics coming off patent, there is also heightened development activity around biosimilar alternatives.

With over 500 dermatology clinical trial sites in operation worldwide, dermatology clinical trials are rapidly approaching saturation in terms of identifying eligible subjects to meet trial enrollment targets. New and less experienced sites have to be identified and trained to meet the changing trial demands. Interest in trial participation also tends to wane in the summer and increase in the winter in direct correlation to the severity of many dermatological conditions and the weather. Summer weather conditions are generally more severe in cold, dry seasons.

The nature of the drug and disease and the requirements of the trial can also impact patient motivation. Drugs that are easy to self-administer are preferred (topical, oral). Injectable drugs that require self-administration or IV infusion in a clinic are less desirable. Similarly, studies that require intense pharmacokinetic/pharmacodynamic assessments and frequent skin biopsies are more difficult to enroll.

There are also other study-related factors that increase the challenges to enrollment and study conduct. Study sponsors often want board-certified dermatologists to serve as study investigators because, though many patients consult their general practitioner first—a physician who may not have specific knowledge and experience in conducting dermatology clinical trials. Finding the right patients can also be an issue. In the dermatology space, the large number of clinical trials are based on visual criteria and frequent skin biopsies are more difficult to enroll.

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Case Study: Rapid Rescue and Decentralization

The need for digital and operational tools that can quickly support a transition from traditional (face-to-face) to remote clinical trial delivery has never been so acute as when sponsor companies experience high attrition due to the impact of the COVID-19 pandemic. However, combining the resources of PPD’s vast network, and our clinical trial operations, regulatory, and data privacy teams, we are also well positioned to develop custom solutions to mitigate the impact of the pandemic threat. The Italian government mandated stringent controls to restrict the movement of people within the country, which would have prevented five patients from attending their trial visits, and thus the sponsor lost vital primary and endpoint data from these patients.

In order to save the clinical trial, it was necessary to leverage a 23 CFR Part 1500 digital solution that could be implemented as fast as possible. In a matter of weeks, the PPD Digital team deployed a visual communication tool using the TeleVisit platform modality itself developed in response to COVID-19. This allowed investigators and patients to communicate online during the pandemic hit. The Italian government mandated stringent controls to restrict the movement of people within the country, which would have prevented five patients from attending their trial visits, and thus the sponsor lost vital primary and endpoint data from these patients.

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patients. We have extensive experience with psoriasis, atopic dermatitis, pemphigus, and glabellar lines. Our dermatology experts regularly work with both large biopharma companies and small/emerging pharma and biotech firms.

PPD has invested heavily in the dermatology therapy area, and we understand the importance of selecting the right sites that can capture the right patients and use rater scoring, which is critical to our dermatology studies. PPD ensures that all investigators are experienced dermatologists with proven success in enrolling the right patients. We have extensive experience with dermato-gists with proven success in enrolling the right patients. We have extensive experience with dermatology space. Our experience with eCOA, ePRO, telemedicine approaches, hybrid virtual trials, e-consents, electronic medical records, and remote source document verification (rSDV), among others, has enabled us to rapidly convert traditional trials to decentralized trials during the COVID-19 pandemic. Indeed, our experiences with eCOA and ePRO have accelerated knowledge capture; the AES database of patients has allowed PPD to quickly pivot in response to unex- pected and changing situational needs, which will enable the support and insight needed to address heightened risks and keep trials on track.

EXPANDING PATIENT ACCESS

Quality clinical trials cannot be achieved without the participation of qualified pa-tients. Given the difficulties in finding these patients and the challenges patients themselves face in accessing dermatologi-cal care, we have taken several steps to help address these issues.

First, we expanded our country and site footprints – including both AES sites and others in the PPD network – with strong dermatology capabilities in the United States, Hungary, Poland, the Czech Re-public, Serbia, Croatia, Italy, Belgium, Denmark, Israel, India, and South Africa. Efforts are also ongoing to train primary care providers so that they can be equipped with the knowledge needed to recom-mend patients for clinical trials. Inclusion of non-specialist sites with solid trial ex-perience provides the opportunity to reach potential patients who often first seek help from their primary doctors.

We have fully leveraged PPD’s in-house capabilities and solutions. Working together, our dermatologists and dermatology dedi-cated physicians across our functions from production to pharmacoeconomics, pharma-covigilance through to AES site personnel.

To reach potential patients, our teams continue to create global awareness through a unique blend of various media platforms, webinars, and other forums. At the same time, we continue to innovate to accommodate evolving study needs, including the use of digital and/or remote patient site activities.

We look at each trial individually to con-sider potential problems, such as season-ality and the placebo effect. We also seek to understand how the medication will be administered (topical, oral, injectable) and how that will impact interest from different patient groups. PPD teams also put themselves in the shoes of the patient. For instance, thinking as deeply as whether or not women will reject participating in a trial with that medication that must dry for two hours before they can apply makeup. Or, in other cases, groups may not participate if the drug is an injectable instead of a pill. A key component of the clinical trial team includes field reps, who are equipped with digital technologies as much as possible and work on-site visits. In addition, accessibility and enrollment can be improved while the burdens on the patient and the investiga-tor site are reduced.

Indeed, the current situation has pre-sented a tremendous opportunity to com-pare results obtained using traditional on-site protocols with those collected remotely using a combination of digital tools. So far, at least one satisfaction sur-vey using rSDV was used with both patients and physicians feel that the quality of care and results obtained during televisits is equal to that of site visits. We also have the opportunity to produce early bench-marks for the accessibility of virtualized and decentralized trials and the impact these tools have on key compo-nents and with sponsor counterparts as we work towards the common goal of successfully implementing and complet- ing high-quality trials that will enable needed medicines to reach the market.

As the clinical landscape continues to evolve, PPD has the resources to conduct trials in many ways, including traditional, hybrid, and decentralized trials, in the dermatology space. Our experience with eCOA, ePRO, telemedicine approaches, hybrid virtual trials, e-consents, electronic medical records, and remote source document verification (rSDV) among others, has enabled us to rapidly convert traditional trials to decentralized trials during the COVID-19 pandemic. Indeed, our experience with eCOA and ePRO has accelerated knowledge capture; the AES database of patients has allowed PPD to quickly pivot in response to unexpected and changing situational needs, which will enable the support and insight needed to address heightened risks and keep trials on track.