

Reacta Healthcare
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A kit solution for the definitive diagnosis of food allergies

Reacta Healthcare produces pharmaceutical grade oral food challenges (OFCs) for diagnosing and establishing the severity of food allergies. The company's standardized OFC for peanut is currently used in clinical trials of food allergy therapies in the UK, EU, and North America.

The global prevalence of food allergies is rising; with estimates that they can affect up to 10% of infants in some countries¹. Because food allergies can result in life-threatening anaphylaxis, they place a daily psychosocial burden on patients and their carers. In addition, families with a food-allergic child bear significantly higher household costs associated with medical care, food choices, and lifestyle changes².

Until recently, the only treatment was food (allergen) avoidance combined with rescue medication (adrenaline injection) to ameliorate symptoms resulting from accidental exposure. Avoiding allergens found in staple foods is challenging and up to 40% of children with food allergy experience a severe allergic reaction³, usually resulting in hospitalization.

Advances in research are starting to yield immunotherapy treatments for the management of food allergies. The first oral immunotherapy for the treatment of peanut (*Arachis hypogaea*) allergy, Palforzia was approved by the US Food and Drug Administration (FDA) in 2019 and by the European Commission (EC) last year⁴. The treatment involves giving patients small but gradually increasing amounts of peanut protein over a 6-month period, followed by a maintenance period of 18 months, to encourage the immune system to develop tolerance and reduce the risk of a severe reaction. "The approval of Palforzia has sparked significant interest in the food-allergy therapeutic and diagnostic space," said Paul Abrahams, CEO of Reacta Healthcare.

Reacta Healthcare, based in Deeside, North Wales, was founded in 2014 to commercialize the oral food challenges (OFCs) originally developed for and used in the EuroPrevall project led by Clare Mills. Since then, Reacta Healthcare has undergone considerable expansion to increase the production capacity of its proprietary peanut OFC under current good manufacturing practice (cGMP) standards at its Medicines and Healthcare products Regulatory Agency (MHRA)-approved site. The team at Reacta Healthcare has also developed new OFCs for the diagnosis of egg and milk allergies that are set for launch in early 2022, with those for other allergens in the research and development (R&D) pipeline (Fig. 1).

Overcoming the shortfalls in food-allergy diagnosis

Typically, food allergies are diagnosed using skin-prick or blood tests to measure specific immunoglobulin E (IgE) antibodies. However, as Abrahams explained, the correlation between these test results and clinical food allergy is poor. Furthermore, these tests provide no indication of the severity of the allergy.

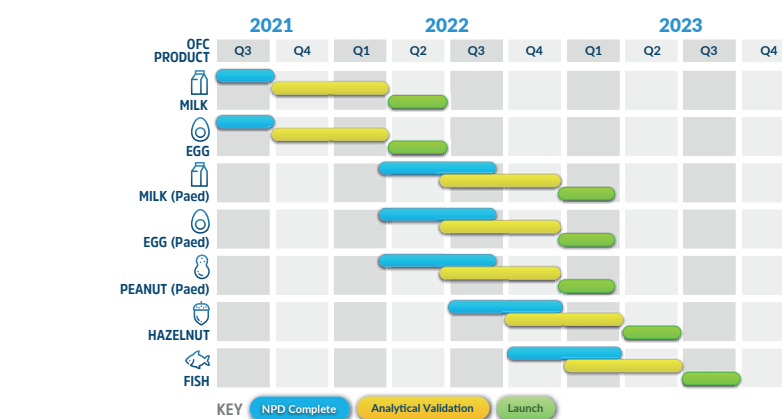


Fig. 1 | Reacta Healthcare's innovation pipeline. OFC, oral food challenges; Paed, pediatric; NPD, new product development.

OFCs are considered the gold standard for food-allergy diagnosis. Challenges comprise the oral administration of the suspected allergen in physician-supervised settings. "Until now there have been no standardized pharmaceutical grade OFCs that allow the reproducible diagnosis of food allergies and their severity," said Abrahams.

Reacta Healthcare's OFC for peanut allergy is currently used in late-stage clinical trials to identify patients eligible for inclusion and to determine their tolerance after therapy. "As the industry expands to develop therapies for other common food allergies such as hazelnut, wheat, and fish, we aim to launch OFCs that meet their needs," Abrahams said.

Reacta Healthcare's tests allow the delivery of specific doses of a fully masked allergen in a proprietary mousse-style formulation.

Once the patient ingests the product, physicians need to monitor them to establish whether they are allergic. By correlating the dose to the time and extent of reaction, the severity of the allergy can be determined.

"The proprietary way in which we mask the allergen is key, as patients are generally very sensitive to the food they are allergic to and can get very anxious even to the extent that they develop subjective symptoms if they detect the taste, texture, sight or smell of it," said Martin Wickham, Chief Commercial Officer at Reacta Healthcare.

Development plans

Reacta Healthcare is in the process of seeking market authorization for its kits as diagnostic products for use beyond the clinical research arena. "In the

next 2 years, we aim to gain approval for OFC kits as diagnostic products for the accurate detection and monitoring of food allergies in the clinical setting," said Abrahams. "With more food-allergy therapies entering the market, it is important to prove that the patient needs treatment and actually responds to it," he added.

Reacta Healthcare's tests are suitable for patients over 4 years old and pediatric versions for infants over 6 months old are in development. "Many food allergies begin early in life, so we are developing tests that meet the regulatory and palatability requirements for very young children," said Wickham.

Abrahams is optimistic about future opportunities. "As more pharmaceutical companies focus on the development of treatments to address the globally rising prevalence of food allergies, Reacta Healthcare is well placed to provide patients with a definitive diagnosis and to determine the severity of their allergy both before and after therapy".

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