



EUPATI CASE REPORT on meaningful patient involvement in R&D and regulatory affairs:

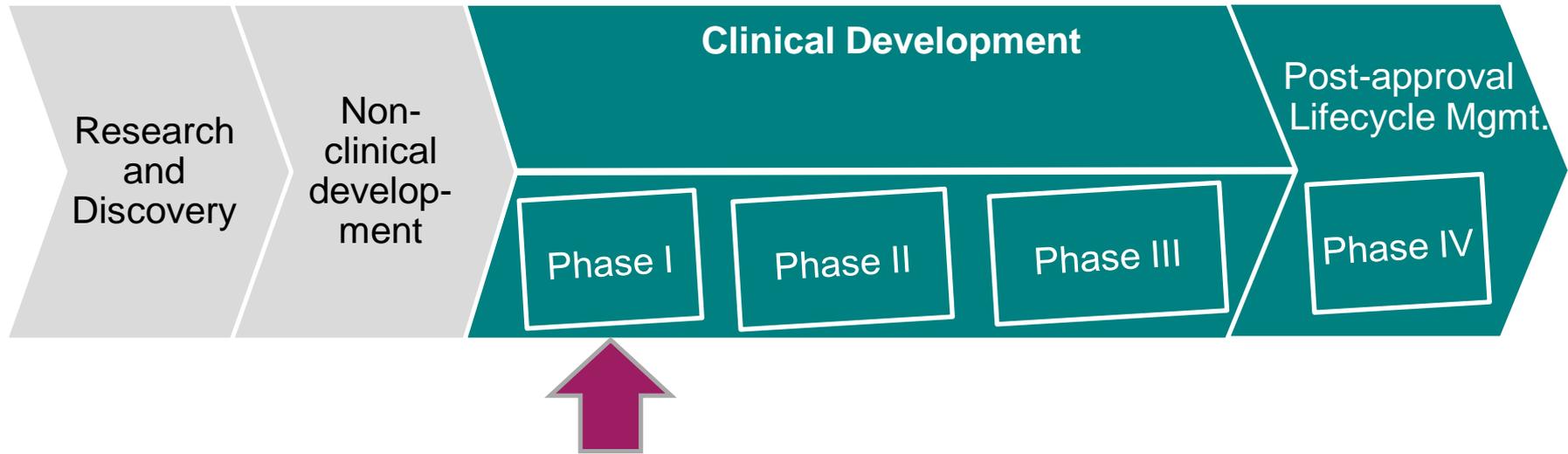
Direct patient insight on Lupus with a focus on cutaneous aspects

PROVIDED BY:
GlaxoSmithKline R&D,
Immuno-Inflammation Therapy Area Unit

Description of the case (how were patients involved in the R&D project? What was the objective?)

- In October 2015, two medical doctors and one scientist from GSK interviewed 5 female patients diagnosed with systemic lupus with cutaneous manifestations, or diagnosed with cutaneous lupus with skin symptoms only - four patients interviewed in Cambridge in the UK, and one patient interviewed over Skype.
- The objective was to hear patients' views on their disease and on research because GSK is planning clinical trials of an investigational medicinal product in patients with cutaneous lupus.
- Patients described
 - a long history of the disease
 - general symptoms that impact on daily life, e.g.
 - become tired very soon,
 - painful joints,
 - cold feet and fingers,
 - prolonged mouth ulcers,
 - feeling isolated or depressed as they cannot always go outside or to work.
 - skin symptoms
 - exposure to sunlight provokes or aggravates symptoms, significantly limiting outside activities,
 - necessity to put on sunscreen even several times a day
 - itchy skin lesions can be thick, occur anywhere on the body including on the head or face, which can lead to social isolation.
 - need for several different treatments, all the time.

RESEARCH/DEVELOPMENT PHASE



Type of patient (advocates) involved

- Patients with personal disease experience
- Expert patient / patient advocate with good expertise on disease, but little R&D experience
- Expert patient / patient advocate with good expertise on disease and good R&D experience
- Other: 1 EUPATI trainee with experience as a patient with the disease under discussion

Challenges and barriers (and how they were overcome, or which ones were unresolved)

The challenge: the interviews were in Cambridge in the UK

- patients who responded had to consider travelling a considerable distance (from the Netherlands and Spain) to participate and were given the option to participate by telephone,
- those who decided to travel were provided with support in making arrangements. Nevertheless, it was a tiring activity for the patients.
- interviews were structured with similar questions for each interview as far as possible. This may have seemed a little strict but it helped to ensure the areas that were discussed were standardised across the patients.
- Following consent, four interviews were video recorded and all audio recorded.
- One interview required an interpreter.

Benefits (how has this collaboration improved R&D process(es) and the R&D outcome(s) or triggered R&D organisational change)

CLEAR DESCRIPTION OF DISEASE IMPACT ON PATIENTS' LIVES

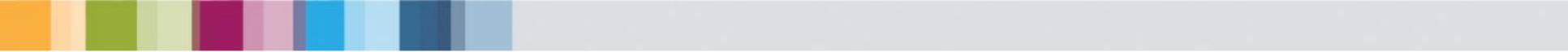
- patients reported a range of general symptoms associated with the cutaneous symptoms, and a range of treatments that they have to use every day.

PATIENTS' DETAILED EXPECTATIONS FROM A NEW TREATMENT

- a new treatment should prevent or reduce the flares – ideally curing them.
- patients would prefer a topical treatment so that they do not have to take another oral treatment.
- ideally they would like the topical treatment to contain sunscreen so that they would not have to apply two creams.
- they would accept intravenous treatment if that meant they would generally be better.

INFORMATION ON ACCEPTABLE CLINICAL TRIAL METHODOLOGY

- with respect to using UV provocation in a clinical trial, they would think about it and may want reassurance that they would not develop a flare.



Discussion and learnings for the company and EUPATI

- The patients were truly inspirational. They have overcome the challenges that the disease has imposed on their lives, and they wanted to help others by sharing their experience.
- It was apparent that the impact of the disease is broad.
- Patients would consider the potential effect of the clinical trial on their disease or their daily routine before considering participating in a trial, to avoid provoking a flare.
- Patients understand that research is required to find new treatments, and they also wish to share their experience to help others through patient organisations.
- **The information that patients shared helped the researchers to progress with designing a clinical trial, which is planned to start during 2016.**