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# An Innovative Approach to Solve an RLD Shortage

## Intelligent Project Management to the Rescue of a Scabies Generic Trial


### The Challenge:

Limited or no availability of the Reference Listed Drug (RLD) for a generic dermatology trial can seriously hinder the feasibility of a study. This was exactly the case in a pivotal, clinical endpoint bioequivalence study for new generic compound to treat Scabies. The approved protocol determined that 140 patients were needed in the per protocol population to prove bioequivalence between the Sponsor's drug and the RLD. The number of doses of RLD required to treat the population randomized to the Reference arm far exceeded the number available for procurement. Study abandonment was looming on the horizon.

### The Solution:

Biorasi tackled this unusual predicament with an innovative approach. Such a complex challenge required undertaking a myriad of multifaceted measures. To preserve as much RLD as possible, Biorasi reduced the number of sites to save on FDA required retains without affecting participation of the necessary number of subjects. Biorasi implemented a very stringent project training plan at study start up, providing rigorous training at the trial sites to ensure strict enrollment of patients with very high potential of protocol adherence. Effective patient engagement (such as providing a bag of quarters that could be used at a laundromat to disinfect all of their clothes, bed sheets, etc.) and follow up (such as offering FAQs and other common tips provided to subjects to ensure they do not get re-infested with scabies) were applied to drastically increase the proportion of PP population in the subject pool, and absolutely minimize the rate of retreatment throughout the study. The combination of all these measures constituted a coherent and efficient solution to the problem at hand.

### The Result:

The study was successfully completed with flying colors on all levels. With 98% compliance and a near 0% dropout rate, the trial exceeded all expectations and effectively treated the required 140 PP population with the available RLD doses. In addition, substantial budget and time recuperation was achieved. Hence, a nearly abandoned trial turned out to be one of the most efficiently completed trials in the Biorasi repertoire. With this accomplishment, Biorasi exhibited a superior degree of innovation, cost consciousness, diligence and persistence in its rendered services to the sponsor as well as provided the public with a cheaper and effective generic drug option for Scabies affected population.

140 PPP

117 RLD Doses

98% Compliance

0% Dropout Rate

**Study Success**

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