BDD Swift

BDD SWIFT for rapid clinical development.

SWIFT accelerates evaluation and optimisation of product performance using in vivo clinical data to direct formulation design in real time.

SWIFT studies enable you to make decisions on formulation changes based on emerging clinical data. This integration of formulation development, GMP manufacturing and clinical testing activities can reduce time from initial prototype development to clinical evaluation in 6 months.

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While extensive research has been performed to develop *in vitro* methods to closely mimic the conditions of the GI tract, *in vitro in vivo* correlation is still difficult to achieve. The classical development route delivers *in vivo* data on product performance at the end of a lengthy and costly development process. If the desired outcomes are not achieved, the process will either need to be repeated with an optimised product or the programme cancelled.

BDD SWIFT provides an alternative to this classical model by enabling product performance to be optimised using clinical data to direct formulation design in real time. This integration of formulation development, GMP manufacturing and clinical testing activities can reduce time from initial prototype development to clinical evaluation within 6 months and dramatically improve chances of success.

Formulation Design Space

Key formulation variables which may impact *in vivo* performance are identified and a range of formulations developed. The boundaries of the design space will be set using cornerstone prototype formulations.

Generally one or two variables will be included in the design space, however up to four variables may be incorporated depending on formulation requirements.

Clinical trials can be run with multiple formulation variables with decisions on formulation changes made between study arms based on emerging interim safety, pharmacokinetic and scintigraphic clinical data.

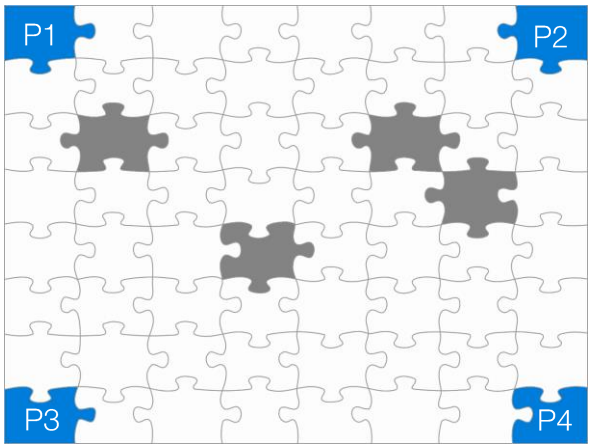
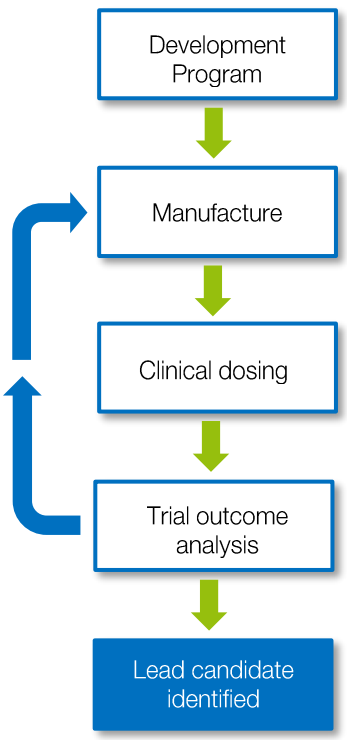


Figure 1. Pre-defined formulation design space with cornerstone prototype formulations



Clinical Trial Design

Clinical protocols are developed to include provisions for the pre-determined design space allowing formulation composition changes within the trial design framework. A decision making algorithm will be described based on desired *in vivo* performance to determine the next dosing period. Formulation selection is based on emerging pharmacokinetic, scintigraphic and safety datasets. The trial design will vary depending on the study objectives but will typically be an exploratory, non randomised trial including multiple dosing periods in an number of subjects.

The BDD clinical trial unit is located within Glasgow Royal Infirmary in the UK. Our dedicated clinical team offers a full clinical trial service package including but not limited to, protocol development, regulatory authority submissions, patient recruitment, clinical conduct, pharmacovigilance reporting, data management and production of an ICH clinical study report.

The clinical trial unit is ISO 9001:2015 accredited and is routinely inspected and audited by clinical trial Sponsors and the UK Competent Authority, the Medicines and Healthcare products Regulatory Agency (MHRA).