

Investigational Medicinal Product [IMP]

An investigational medicinal product is an active ingredient or placebo that has been pharmaceutically formulated (prepared) for human use which is being tested, or used as a comparator, in a clinical trial.

Typically IMPs have not yet received marketing authorisation, however in some circumstances they may be products that have been authorised:

- when they have been made using a different formulation than that which is authorised (e.g. different dose),
- when the authorised product is to be used as the test substance or comparator in a clinical trial,
- when used for an unapproved indication (off-label), or
- when used to gain further information about an approved use.