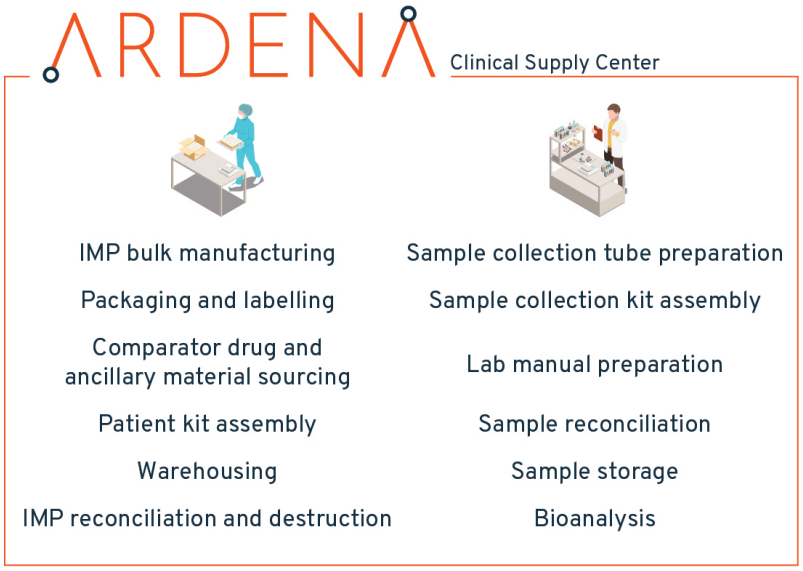
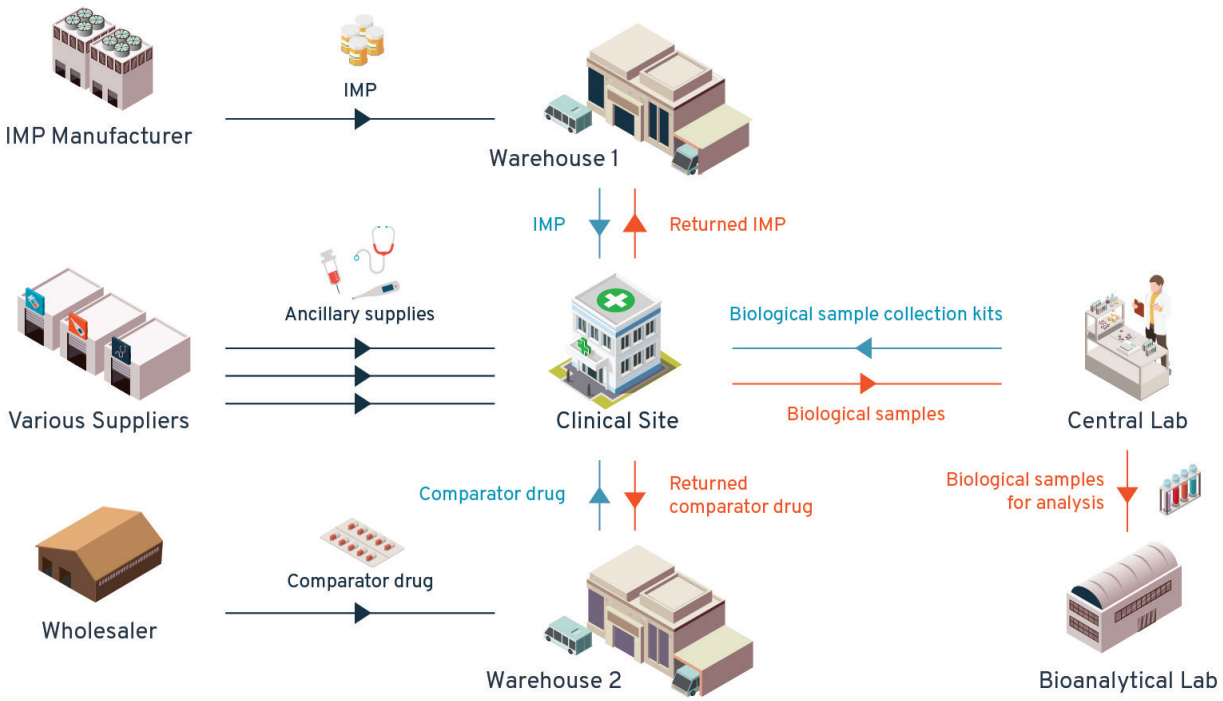
How to save significantly on early-phase clinical supply logistics?



Efficient supply of investigational medicinal products (IMPs) is key to ensuring patients are dosed on time and clinical trials run efficiently. In addition to the IMP, a wide variety of materials are needed to support a clinical trial, including placebo drug product, comparator drug product and ancillary supplies (e.g. diagnostic tests, medical equipment, consumables, etc.). In early-phase clinical trials, all these materials are typically shipped from different suppliers to the clinical centers. The hospital pharmacy staff then prepares prepare tailor-made patient kits that contain IMP, placebo and/or comparator drug product and the ancillary materials.

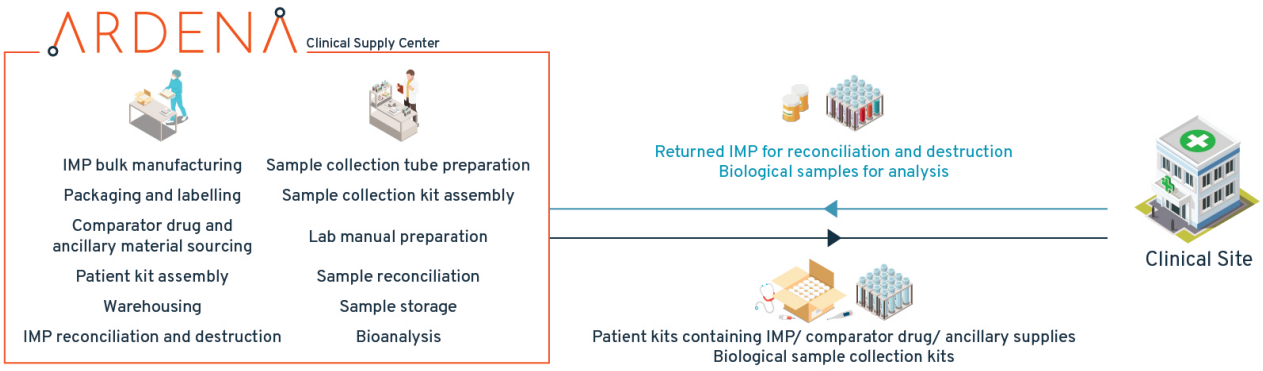
In addition to these patient kits, the physician will also receive sample collection kits which contain a customized selection of biological specimen collection tubes (blood, urine, tissue, etc.), aliquoting tubes, needles and various sample collection materials. These sample collection kits are usually prepared at the central laboratory (working under supervision of the clinical research organization) and then dispatched to the clinical centers. Assembly of these kits entails a great deal of customization and requires involvement of the bioanalytical laboratory.

Timely delivery of the forecasted demands of all these materials implies meticulous management of multiple manufacturers, wholesalers, warehouses and couriers. The supply chain management is further compounded by the fact that IMPs are shipped on an on-demand basis as hospital pharmacies generally have low storage capacity. Biological samples in turn may require frequent shipment from the clinical center to the bioanalytical laboratory to ensure analysis prior to degradation. The sheer number of shipments needed to maintain this multi-vendor supply chains drives up logistics costs considerably.



Traditional early-phase clinical supply chain involving multiple parties

The clinical supply center at Ardena integrates the IMP production, sourcing, packaging and labelling, logistics and bioanalysis function. Based on the clinical study design, our cross-functional team assembles both patient kits as well as sample collection kits. These are then sent simultaneously to the clinical centers. When we organize return shipments to our clinical supply center, we combine, whenever possible, IMP overages and biological samples. This combined shipment strategy decreases courier costs by approximately 50%. Having the oversight of the entire clinical supply chain also enables us to considerably reduce the project management burden for the study sponsor.



Early-phase clinical supply chain at Ardena