



Understanding Late Phase



CHILTERN LATE PHASE

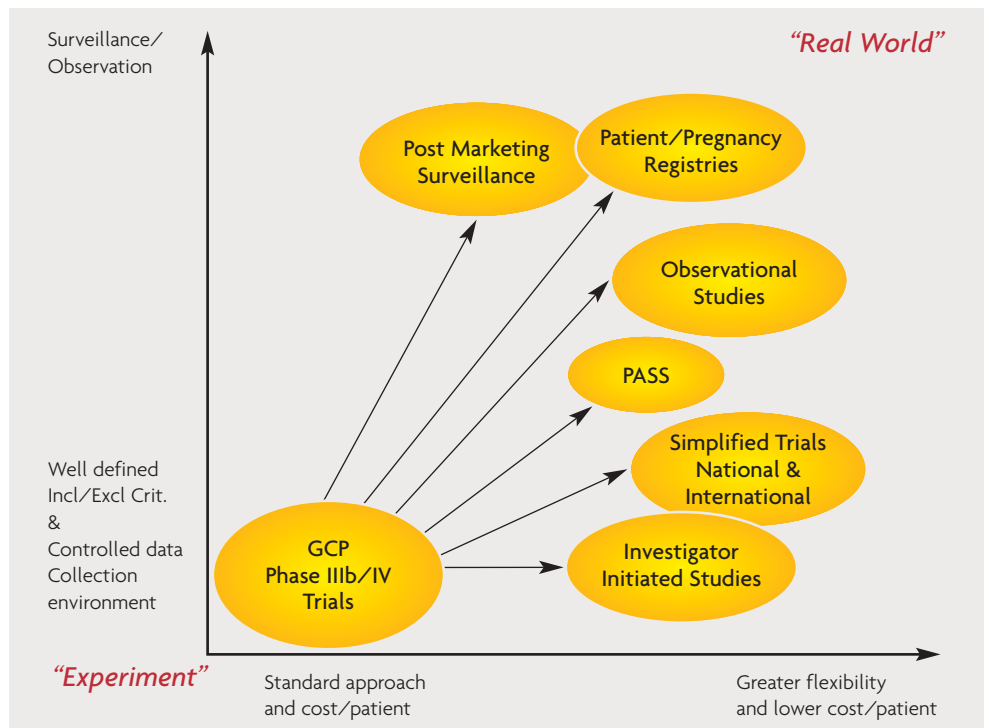
The success of a new product is judged by more than its promising clinical trial results. It needs to achieve its commercial objectives to justify initial investment. Chiltern Late Phase has focus in both local and national studies as well as large global programs. For example, Chiltern is currently performing registries from 100 patients to over 20,000 patients in a global setting.

Our Global Late Phase Group deploys dedicated specialist Project Managers and experienced clinical development professionals to deliver services from consultative design and data collection through robust reporting. Our dedicated group focuses on providing specific services designed to support products from the point of approval/marketing authorization through launch and beyond.

Our global expert teams provide Phase IIIb and IV, non-interventional, observational, epidemiology, investigator-initiated trials and registry services worldwide. Chiltern also performs regulatory mandated studies, providing long-term safety surveillance in a real-world setting with dedication and commitment.

LATE PHASE CAPABILITIES

- Disease/product registries
- Pregnancy registries
- Post marketing studies
- Post approval safety study (PASS)
- Risk management programs
- Patient reported outcomes
- Phase IIIb/IV studies
- Medical/drug utilization studies
- Expanded access programs (Compassionate use, named patient programs)
- Global call center
- Epidemiologic and retrospective studies





DATA COLLECTION

Chiltern utilizes in-house systems to implement Patient Reported Outcome (PRO) data collection strategies in a variety of ways including telephone data collection via Computer Assisted Telephone Interviews (CATI).

As a Late Phase speciality, we apply processes for more remote support in site initiation and monitoring to deliver cost savings and quality results.

REMOTE SERVICES

Chiltern offers a Global Call Center (GCC) which serves as our global remote services center to operationalize global projects. This capability is an integral part of successful project management and the implementation of remote monitoring and site management support. We use web-based applications for tracking and follow up of calls from any location. This allows us to distribute remote services quickly and efficiently throughout the world.

Other services provided by our remote services specialists comprise of help desks for Electronic Data Capture (EDC) studies using a variety of EDC systems.

Help desk services are operational in our offices in US, Germany, France and India, covering most global study needs across the time zones.

In addition to EDC support, we offer project related support for Late Phase programs such as for CATI and other support services. The key advantage of the GCC is that it can be used as a stand-alone support for our clients or part of a full study program support.

LATE PHASE OPERATIONS

The hub of Chiltern Late Phase operations resides in Germany, Spain, France, UK and US. This provides an excellent base on which to involve our global offices to provide extensive geographic coverage for access to diverse patient populations.

Study leadership is provided by global and national Project Managers who are supported by functional operational teams globally.

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