Bionical Emas

Fact Sheet

Benefits of Bionical Emas Phase 1 Services

A guide to the specialised clinical research services, provided by Bionical Emas, in support of a successful delivery, for Phase 1 clinical studies.

Outline:

Phase I clinical trials are a key step in any pharmaceutical company's clinical drug development process. Phase I studies are undertaken in dedicated units and those Phase I units typically provide services, centered around the volunteer. However, there are additional activities, outside of the interaction with the volunteer, that are required for a Phase I study to be successful. This is where Bionical Emas can be of help.

Clinical Operations:

- Data monitoring undertaken by a specialist Phase I Clinical Research Associate (CRA) team. Monitoring can be undertaken on site or remotely
- Study Project Management
- Document management including Electronic Trial Management File (eTMF)

Pharmacovigilance:

- PVG Study documents
- SIV Training
- Safety database set-up and management
- SUSAR reporting

Medical Services:

- Protocol development
- Clinical study reports
- Safety and medical monitoring
- Establish and run Data Monitoring Committees (DMC)

Additional Services:

- Regulatory services
- Clinical trial supply

Bionical Emas

Bionical Emas extensive experience with specialist Phase I units

20+ years — Experience working on Phase I studies and working with specialist Phase I units in the USA, Europe and Asia Pacific.

60+ — Supporting over 60 Phase I studies a year.

35 — Supported over 35 different therapeutic areas.

100% — 100% SDV (Source Data Verification) of data for over 2000 patients

Benefits of using Bionical Emas

- An experienced, established and dedicated Phase I team, experienced in managing the rapid start up timelines of Phase I studies. From contract to Site Initiation Visit (SIV) within two days.
- A cost-effective business model tailored to meeting the specialised requirements of Phase I studies.

Bionical Emas is the only Clinical Research Organisation (CRO) that provides services to support, clinical drug development, early access programs and clinical trial supply.

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