DELPHINIUM

Truth | Protection | Health | Ambition

About DELPHNINIUM

DELPHINIUM is a flexible, boutique CRO with its own research clinic and pharmacy. We combine experience, innovation, and a personal approach to deliver reliable, high-quality clinical research with competitive pricing.

Experienced team, personal approach

- PI and team performed **50+ HV** and patient studies
- **Direct communication** with PI and staff

Fast and pragmatic delivery

- Submission targeting **~6 weeks** to approval
- **Lean budgets**, timelines & recruitment plans

In-house clinical trial support

- Real-time data entry with **ClinSpark eSource**
- On-site **GMP pharmacy** for secure and flexible dosing

Our facility

12-Bed Clinical Research Unit
Ideal for various study designs and subject accommodations

Located on the premises of the University Medical Center Groningen (UMCG), NL
Direct access to a wide range of medical departments and specialists.
Standy-by Intensive Care Unit for high-risk studies

Fully Equipped Facilities
With a dedicated in-house study team, validated equipment, and the integrated use of ClinSpark as e-source and EDC, we ensure precise and compliant support for a broad range of clinical trial designs

On-site GMP Pharmacy
Licensed for manufacturing oral dosage forms and extemporaneous oral and IV preparations
Qualified Person as part of the in-house pharmacy team

Our facility

12-Bed Clinical Research Unit

- Supervision room: direct visual contact with all subjects for high-risk studies.
- Smaller room for low-risk studies; more privacy.
- Privat examination room for special assessments.

Processing lab

- Set-up with all standard equipment.
- Storage (fridge, -20°C and -80°C)
- Fully integrated with ClinSpark.

Comfortable and welcoming environment

- The living room offers volunteers a comfortable space to relax and enjoy a pleasant stay, even during longer in-house studies.
- Enclosed garden.

Our facility - On-site Pharmacy and Qualified Person

- **Licensed for Manufacturing Oral Dosage Forms**
  Hard capsules and liquids, adaptable dosage form development to support every trial phase
- **Import and QP Release Services**
  Accelerate EU trial start with seamless import and compliant release
- **Manufacturing, Packaging and Labelling**
  Integrated clinical supply solutions, from batch to box
- **Extemporaneous Oral and IV Preparations**
  On demand oral and sterile compounding for specific dosing
- **Storage for -20°C, 2-8°C and 15-25°C**
  Secure, GMP-compliant with real-time temperature monitoring

Expertise in Phase I clinical trial

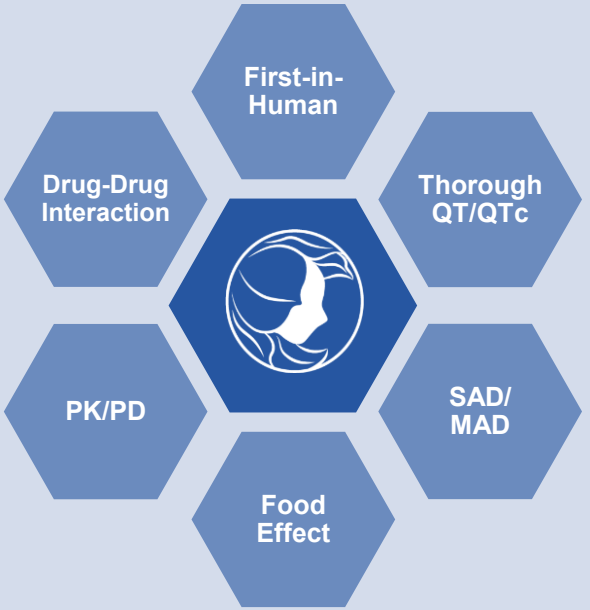
We offer extensive expertise in **early-phase clinical research**, with a strong focus on a broad spectrum of Phase I studies.

Our focus is on **studies in healthy volunteers**, supporting a wide range of therapeutic areas. We have built **particular expertise** in:

- *Cardiology*
- *Neurology*
- *Nephrology*
- *Allergology*
- *Hematology*
- *Rare Diseases*

DELPHINIUM provides direct access to **senior early-phase experts** (>60 years of experience).

DELPHINIUM's agile structure enables **pragmatic decisions, flexibility** and **swift issue resolution**, backed by a collaborative **personal approach.**



Regulatory

DELPHINIUM is based in the Netherlands, benefiting from a supportive and **efficient regulatory environment**.

Clinical trial submissions fall under the EU Clinical Trial Regulation (CTR) and are processed via the Clinical Trial Information System (CTIS).

Part I and Part II can be submitted **simultaneously**, **streamlining** the approval process.

DELPHINIUM's partnership with a local IRB/EC allows **approvals** to be obtained in **~ 30 working days after submission** — much faster than the **standard 108-day** timeline resulting in a shorter overall study start-up.

ClinSpark: Real-time data entry

- **Real-time Capture:** ClinSpark enables direct data entry at the point of care – no paper source required
- **Data Accuracy & Quality:** Built-in checks reduce errors and ensure protocol compliance from the start
- **Regulatory Compliant**: 21 CFR Part 11 validated and fully audit-trail enabled
- **Inhouse Design and Programming**: Agile adaptation to procedural improvements and protocol amendments
- **Integration Ready**: Seamlessly connects with lab systems, eCRFs, and sponsor platforms.
- **eSource and EDC system**: ClinSpark can be used as e-Source and EDC system with direct data cleaning.

Real-time access

Easier decision making

Shorter timelines

Lower budgets

Effective Recruitment Strategy

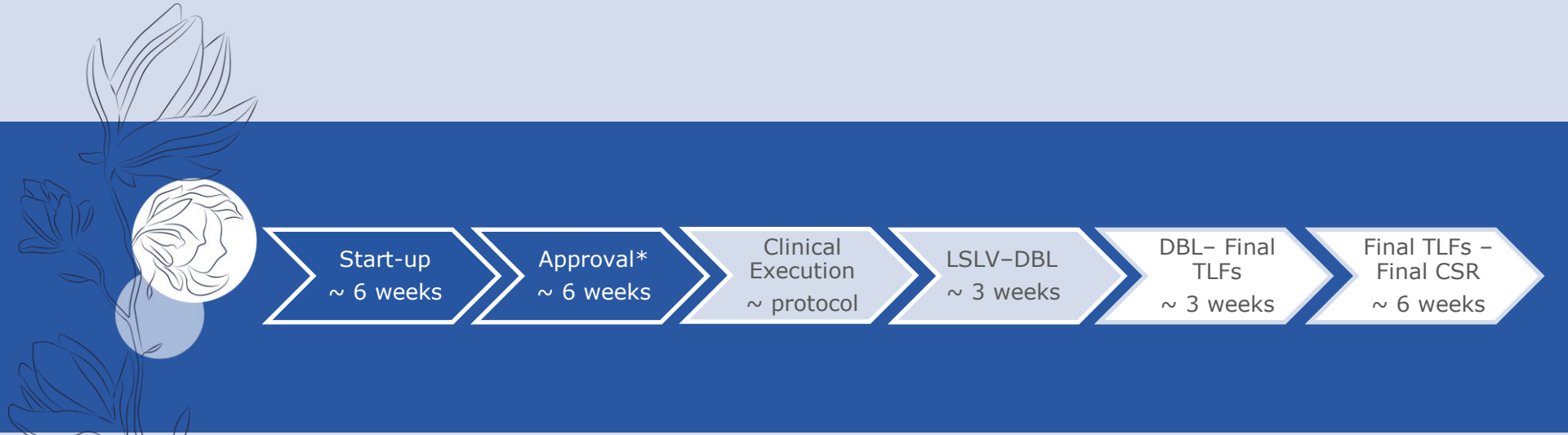
- An established database of healthy volunteers
- Advertisements on website and social media
- Additional recruitment strategies based on your need
- Include one or more spare subjects to ensure sufficient volunteers on the day of dosing
- Maintain in contact with volunteers to ensure scheduled appointments are met

Comprehensive Full-Service

To enhance our offerings, we collaborate with **trusted partners** for specialized services, ensuring **high-quality** results and streamlined operations. This integrated approach allows us to leverage expert resources while maintaining flexibility and efficiency, **providing tailored solutions** that **meet your specific needs.**

- Medical Writing
- Data Management
- Clinical Monitoring
- Biostatistics
- Bioanalysis
- Pharmacovigilance
- Medical Monitoring
- Trial Master File

General project timelines



** Timeline for Single Center, Single Country studies.*

Thank you

Interested in learning more about DELPHINIUM?

www.delphiniumcro.com

info@delphiniumcro.com

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