




# clinville



Clinville Ltd, a pan-European investigational site management organization (SMO), provides the crucial link between the health-care sector and the pharmaceutical industry for quality-driven and timely drug development.

Clinville believes that advanced technology, combined with professional competence, dedication to the work and high ethical standards are the key to future success.

**Pan-European site management organization (SMO)**

**Pharma Industry Information  
Patient Information  
Investigator Information  
Nurse Information**

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The development of new molecular entities requires global clinical research & development: targeted, transparent, standardized and fast-track research. The highest quality standards, keeping to all deadlines and maintaining costs within a given budget are of paramount importance.

Clinville is a pan-European investigational-site management organization that maintains a network of independent practising physicians and pharmacies (investigational sites) with a variety of specialities to conduct next-level clinical studies using electronic trial management and has a managing staff with hands-on international pharmaceutical R&D experience.

The value of Clinville lies in its total dedication as an e-SMO (electronic site management organization) making the intricacies of performing clinical studies for the pharmaceutical industry more transparent, calculable and controllable.

Clinville offers the following services:

- Feasibility study: up-to-date information on investigator's patient capacity per therapeutic area
- Site identification
- Clinical trial set-up and management
- Patient recruitment with reduced enrolment risks by using e-trial management
- Project management and coordination
- Monitoring according to ICH/GCP
- Real-time patient data (e-trials)
- All the benefits of e-trial management (immediate corrective action in the event of erroneous data, less monitoring travel, higher data quality)
- Training courses for all people working with clinical trials.

### Information for the pharmaceutical industry

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**Have you ever wondered how drugs are developed?**  
During the development of new treatments, several carefully controlled studies must be carried out, either in clinics and hospitals or in private medical practices. The best doctors are selected to conduct these studies.

**Have you heard of clinical trials but weren't sure how you could take part?**  
You and your doctor are the only ones who can decide whether a clinical study is right for your particular medical condition. Clinical trials are a treatment option for many people; however, it is important for you to understand the benefits and risks of taking part in such trials. The benefit is that you'll receive the latest treatment free of charge during the study period. The medication or treatments on trial are only available to the patients taking part in the study. In addition, you are regularly given thorough check-ups by your doctor - often more frequently than non-study patients. However, the new medicinal product or treatment might not be better than standard care, or it may have undesirable side-effects.

**Why should you consider taking part in a clinical trial?**  
For two major reasons: Firstly, to be given access to experimental treatment for a serious or life-threatening condition long before it is approved and available on the market. Secondly, you might give other people suffering from the same condition as you the opportunity to improve their treatment options.

**Do you know how you are protected within a clinical trial?**  
Clear guidelines, called clinical study protocols, are drawn up to make sure that patients are not put at any unnecessary risk. These protocols are carefully reviewed by a committee of experts and lay people (ethics committee) before a study is allowed to commence. However, since you are a volunteer, you have the right to refuse treatment at any time during the clinical trial and leave the trial for any reason without any penalty.

**Information for patients  
and potential trial participant**

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Many investigational sites which generate a significant share of their revenue through clinical studies are looking for well-trained study nurses. A good study nurse often acts as the organizational manager for a clinical trial. Clinville is a specialized investigational-site management organization (SMO) with a network of independent practising physicians and pharmacies who conduct clinical trials using web-based data management (e-trials).

**What is the advantage for me to work with Clinville?**

Many of the tasks in a clinical trial are delegated to a study nurse whose important role involves responsibility for handling direct communication with patients, administrative matters, and drug accountability. The study nurse is often also the main contact with the sponsor company, the contract research organization (CRO), or the SMO. In order to fulfil such an important position, you will receive thorough, continuous training in GCP/ICH and all other study-related regulations.

Should you already be a study nurse and wish to brush up your current knowledge or learn more about specific topics please contact us for the details of our training programme.

**Information for  
clinical research nurses**

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A photograph of a hospital hallway with several people, including a doctor in white scrubs and a woman in a business suit. A white wireframe grid is overlaid on the image, creating a sense of digital connectivity.

**Do you have a keen interest in research and development in the pharmaceutical industry?**

**Would you like to offer your patients additional treatment options or the latest medication as part of a clinical study?**

**Are you interested in other professional health-care options?**

**If the answer is YES then you are probably interested in becoming a clinical-trial investigator.**

**What are the benefits for me/my site when registered with Clinville's database?**

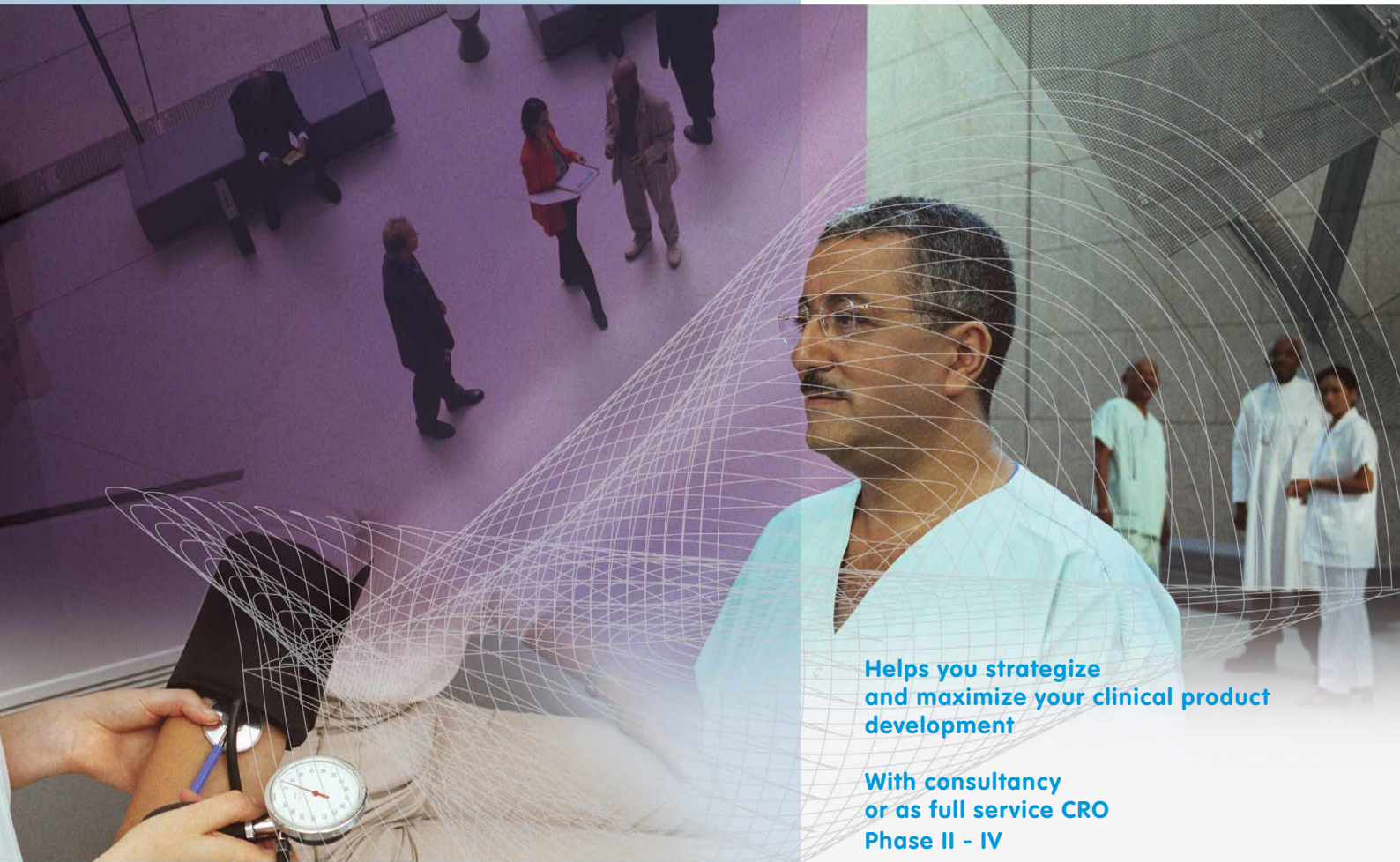
**Clinville is a specialized investigational-site management organization (SMO) with a network of independent practising physicians conducting clinical studies mostly using web-based data management (e-trials). E-trials enable studies to be performed faster, at a higher level of quality, with less time-consuming monitoring and data-clarification and a greater level of standardization between studies. Sites trained in e-trials are still rare and very attractive to the pharmaceutical industry and clinical research organizations (CROs).**

**Information for  
potential investigators**

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Clinical Research  
& Development  
of Pharmaceuticals Ltd.



**Helps you strategize  
and maximize your clinical product  
development**

**With consultancy  
or as full service CRO  
Phase II - IV**

**Your challenge is:**

**Getting your new molecular entity on a fast track to market.  
Adapting to constant changes in the regulatory and marketing environment.  
Respecting your cost and resource constraints for R&D.  
Being able to track many different projects, while keeping control of all of them.  
Being everywhere at the same time!**

**We have one solution: CRDP**

**We combine efficiency and reliability with the latest technology  
and a Pan-European Site Management Organisation (Clinville Ltd.)  
to ensure optimal quality and timelines for our services and a continuous  
transparency in the communication with the sponsor.**

**We offer a contractual guarantee that we will deliver within budgets  
and on time - with penalties if we do not make the grade and a bonus  
if we are ahead of the deadlines.**

**Our services are:**

**Clinical research plan design  
Elaboration of study design  
Protocol writing  
Case report form creation  
Set up of e-trials  
Organization of drug packaging  
Clinical trial authorizations  
Investigator recruitment  
Monitoring  
Data management  
Statistical analysis  
Final study report writing**

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