



EasyClin User Manual Feasibility

- **For Investigators** -

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1. Welcome

In the year 2017 and in view of the imminent implementation of the European General Data Protection Regulation, the question arose how feasibility studies should be carried out in accordance with the new regulation and more precisely how to give all stakeholders full access to their own data. Based on these considerations, we have devised a system to carry out these evaluations quickly, cheaply, and securely. We are proud to make this product available to you as an independent system. The automation of the process will provide you with more time and help to better control your personal and facility data.

2. Abbreviations and Definitions

CRO	“Clinical Research Organization” stands for all teams or people implementing and financing clinical research projects (sponsors) or organizing / operation clinical research projects on their behalf (CRO`s, consultancies etc.).
ICH-GCP	International Conference on Harmonization – Good Clinical Practice
NDA / CDA	Non-Disclosure Agreement / Confidentiality Agreement
EU-GDPR	European General Data Protection Regulation,
Investigator	Stands for all on site physicians
QA	Quality Assurance
Dashboard	Provide at-a-glance views of key performance indicators (KPIs) relevant to an objective or business process

3. Invitation to participate

Dear Investigator and user of EasyClin© feasibility. This platform will give you and your colleagues a global visibility to participate in clinical research projects.

We´d like to ask you to let your colleagues participate and explore the advantages of EasyClin© themselves, by inviting them to register on our platform for free.

If you are happy with EasyClin© tell it to others, if not contact us. We are constantly working on improvements and are happy to receive customer feedback.

Sven Engel, CEO – CIO SynapCon Ltd. Seko Williams, COO SynapCon Ltd.



This project has received funding from the European Union's Horizon 2020 research and Innovation programme under grant Agreement No 691546

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5 Introduction

This tool offers a simple and cost-effective way to evaluate the feasibility of clinical projects at different study centers. This reduces and controls the risks associated with clinical project placement, avoids errors and, in the best case, prolongs product marketing cycles by bringing the products under investigation to the market earlier.

5.1 Intention

It is our concern and aspiration to provide small and medium-sized companies with professional tools for clinical product development. SynapCon have decades of experience in the development of IT for medicine and the clinical development expertise to do so. This experience enables us to offer standardized yet customized solutions. We strictly pursue our

common vision to make medical innovations available to patients and physicians as quickly as possible.

5.2 Customer

The system is aimed at all researchers conducting clinical trials and under constant improvement. This applies to all prospective studies of all clinical phases, as well as any kind of non-interventional study.

Main addressees are universities and researching clinics, patient organizations, pharmaceutical and biotech companies, medtech and diagnostic companies.

5.3 Investigators

For potential investigators, registration and participation in the selection procedures does not entail any costs for the use of the system.

Important Note: Investigators performing own clinical trials (e.g. multicenter investigator-initiated trials) are invited to register as a CRO (Customer) additionally.

5.4 Feasibility Studies

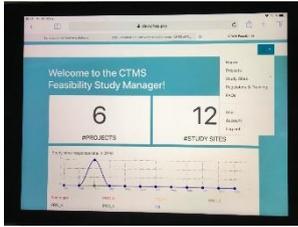
Feasibility Studies are pieces of research done before a main study in order to answer the question “Can this study be done?”. They are used to estimate important parameters that are needed to design the main study. The design of a feasibility study generally involves listing those parameters which are uncertain and describing the methods for improving their precision so that the main study will have a better chance of success. Examples of such parameters include:

- standard deviation of the outcome measure, which in some cases is needed to estimate sample size
- willingness of participants to be randomized
- willingness of clinicians to recruit participants
- number of eligible patients
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
- availability of data needed or the usefulness and limitations of a database; and
- time needed to collect and analyze data.

Feasibility studies for randomized controlled trials may not themselves be randomized. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main study.

Feasibility studies for randomized controlled trials may not themselves be randomized. If a feasibility study is a small randomized controlled trial, it does not necessarily need to have a primary outcome or power calculations. Instead, the sample size is often used to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

5.5 Platforms



EasyClin© feasibility works on various browsers and hardware. They include Mozilla Firefox, Google, MS Edge, and Safari as well on tablets using IOS 12.X.X and Android 9 (Pie). In case of problems please try another configuration.

EasyClin© feasibility is available as a cloud solution. Our servers are in server farms in Germany and are subject to the strictest security requirements.

6 First Steps

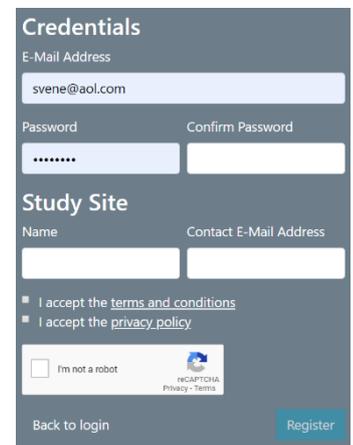
6.1 Registration



The registration form features the SynapCon logo at the top. Below it, the text reads "Welcome to EasyClin Feasibility!". There are two input fields for "E-Mail Address" and "Password". A "Login" button is positioned to the right of the password field. Below the password field, there is a link for "Not yet registered?" and a "Register as Sponsor or register as a Study Site" button. At the bottom, there is a logo for PERMIDES and a text block stating: "This project has received funding from the European Union's Horizon 2020 research and Innovation programme under grant Agreement No 691546".

Investigators can register pro-active on the entry portal to the global investigator list or upon invitation to participate in a feasibility project.

Once you have completed the information needed for you registration you will receive an email confirming the registration (6.5 Confirmation).



This section shows the "Credentials" and "Study Site" parts of the registration form. The "Credentials" section includes an "E-Mail Address" field with the value "svene@aol.com", a "Password" field with masked characters, and a "Confirm Password" field. The "Study Site" section includes a "Name" field and a "Contact E-Mail Address" field. Below these fields are two checkboxes: "I accept the [terms and conditions](#)" and "I accept the [privacy policy](#)". A CAPTCHA section follows with an "I'm not a robot" checkbox and a CAPTCHA image. At the bottom, there are "Back to login" and "Register" buttons.

6.1.1 Invitation before Registration

Khruska Clinic Mangold
Prof Dr. Immsen
Peterson Street
34293-Karlsdorf
CH



Personal Invitation to Contribute to a Clinical Research Project

Safety, tolerability, pharmacodynamics and pharmacokinetics
of escalating single oral doses of 25, 50, 100 and 200 mg XXX
tablets in subjects with coronary heart disease.

Dear Prof Dr. Immsen,

Regarding a planned clinical study, we collect information via questionnaire to investigate the potential of investigators / centers to support this project with high medical relevance.

After evaluation of public sources (internet, publication, literature) we thought that you and your team could be interested in this clinical project.

Please visit [CTMS Feasibility](#) and login with the following credentials, to get access to a personal space of the feasibility platform EasyClin®.

Username: info@synapcon.com Password: v2WnHTNn

Please kindly follow the instructions and complete the questionnaire. Please be kindly reminded that the deadline for answering is 28-03-2019. From our experience the time needed to answer all questions is 15 to 30 minutes.

Thank you in advance for your cooperation.

Yours sincerely,
Pharma & MedTech Development

With your personal invitation from the sponsor or contract research organization of a clinical research study you will receive the log in details to EasyClin(c) feasibility. After you log in to the system you will be asked whether you'd like to become part of the global researcher's community or not. In every case you remain the owner of your personal data. This means also you can refuse the invitation and you can delete the whole data-set.

If you'd like to revise your decision you can register again any time free of charge on the global list.

6.1.2 Invitation after Registration

Regarding a planned clinical study, we collect information via questionnaire to investigate the potential of investigators / centers to support this project with high medical relevance.

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Please kindly follow the instructions and complete the questionnaire. Please be kindly reminded that the deadline for answering is 28-03-2019. From our experience the time needed to answer all questions is 15 to 30 minutes.

Thank you in advance for your cooperation.

Yours sincerely,

In case you are already registered on the global list you will be invited without any additional log in details. Please use your known login information.

6.2 Terms and Conditions

Our terms and conditions explain the basics of our contract and protect intellectual properties. Please read them carefully before agreeing to them.

6.3 Privacy Policy

Our privacy policy informs about the following important aspects when using our services:

- I. Information about us as controllers of your data
- II. The rights of users and data subjects
- III. Information about the data processing

Please read them carefully before you agreeing to it

6.4 reCAPTCHA

A service that protects our website from spam and abuse. reCAPTCHA uses an advanced risk analysis engine and adaptive challenges to keep automated software from engaging in abusive activities on our site. It does this while letting your valid users pass through with ease.

For further information please click below the reCAPTCHA logo and follow the link to Google's privacy policy and terms.

6.5 Confirmation



Complete the registration by clicking
On the link in the email you received.



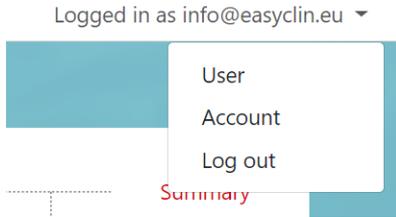
6.6 Login



Login by pressing the "Login now" button when
entering the system, the first time

Enter your email address and password and
login to the system





Please complete your name. You may also change your password here.



6.7 Account

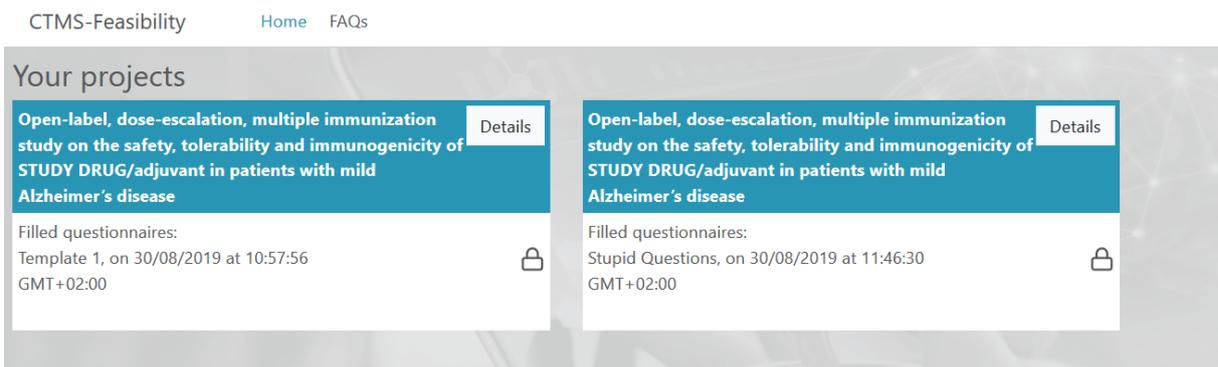
Please complete your registration information. The queries marked with * are essential to ensure your proper involvement in the process (to be considered for studies).

You will be reminded to complete your essential information before proceeding.



7 Dashboard

After logging in to the system you will first see all projects you have participated in in the past, as well as all active projects.



8. Regulatory & Training

All information you may need to use the system is available under <https://www.synapcon.com/study-site-selection/>. The user manual is available for download, as well as further information about our system and feasibility studies in general.

A special regulatory training or introduction to the system is not necessary. The system will guide you through the process.

9. Frequently Asked Questions

Here you will find a collection of possible questions and requests from users. We try to record all questions promptly and answer them comprehensively. Please address your questions to service@easyclin.com.

Frequently Asked Questions

Q: How many projects can I keep running in parallel?
A: The number of project and users on all platforms of our hybrid system is unlimited.

Q: What kind of platform is adequate for my company?
A: It depends on the number of projects you are running and your compliance rules. The following platforms are possible (cloud solution, private cloud solution (actively managed) and a private installation. For more information please kindly contact our sales department (sales@easyclin.com).

For further information please contact service@easyclin.com

10. Global Study Sites Registry

The companies that use the system can select investigators from the global list. All investigators on this list have agreed to be eligible. Most of the investigators on this global list have experience in clinical trials. However, all the information provided here comes from the study centers. We do not review the content in any way and accept no responsibility for the information provided.

There are two ways for the study sites to appear on the global list.

1. via pro-active own entry
2. by invitation to participate in a feasibility study
The decision to appear on the global list after being invited by a CRO is made proactively by the Study Centre.



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Thank you in advance for your cooperation.

Yours sincerely,

Investigators from a personal list without an own account at the global list receive this invitation via email.

The recipients will be asked to change their password after the first login.

After opening the system investigators will be asked to move to the global list. This will increase your visibility and help in creating further business for your organization.

Investigators already registered on the global list receive this invitation via email, without new access details.

11. Closing Remarks

We are convinced that we have presented a tool for managing feasibility studies that is convincing in all respects. If you still have classic inquiries (bypassing current data protection standards) addressed to you, please inform your business partner about our system.

For the first time you now can have an overview of all inquiries at one place. The standardization gives you the freedom for more important activities within the scope of your medical activity and relieves your team.

Please direct your questions to: sales@easyclin.com

Your EasyClin Feasibility Team

July 2020

Frankfurt am Main, Germany