EASYCLIN®

EASYFEASIBILITY®

EASYTMF®

EASYISF®

EASYCRF®

CLINSTORM®

STANDARDIZED | EASY TO USE | AFFORDABLE | DIGITAL CLINICAL TRIALS

The control center for clinical trials

SYNAPCON

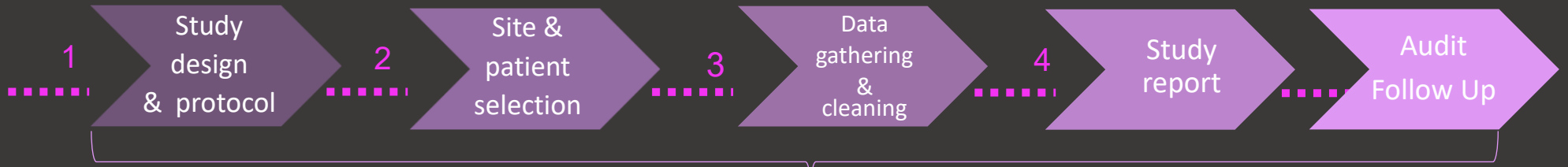
Why Use a CTMS?

Clinical trials are a complex in a demanding environment.

Specific needs:
- Worldwide contributions, collaboration and communication
- Pre, peri and post project performance requirements
- Extensible, scalable and stable (availability >98%)

Scenarios:
- Single centre investigation
- Multiple centre investigation
- Trials that grow into larger investigations

What we offer:
- The control center for clinical trials.



Control and fulfill your milestones!

EASYCLIN®

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EASYCLIN® - the Control Center

Easy, Affordable, Secure, and Compliant.

We deliver full coverage, end-to-end, software services for your clinical trials.

EASYFEASIBILITY®

Feasibility portal: Study site selection

Web portal to pre-select, invite and onboard centres worldwide

EASYTMF®

Trial Master File:

Realtime Document, User and Project Management.

EASYISF®

Investigator Study File:

Realtime tracking, KPI and risk metrics

EASYCRF®

Case Report File:

Realtime tracking, KPI and risk metrics

In development

CLINSTORM®

Clinical Insights and Artificial Intelligence:

Realtime tracking of opportunities and development

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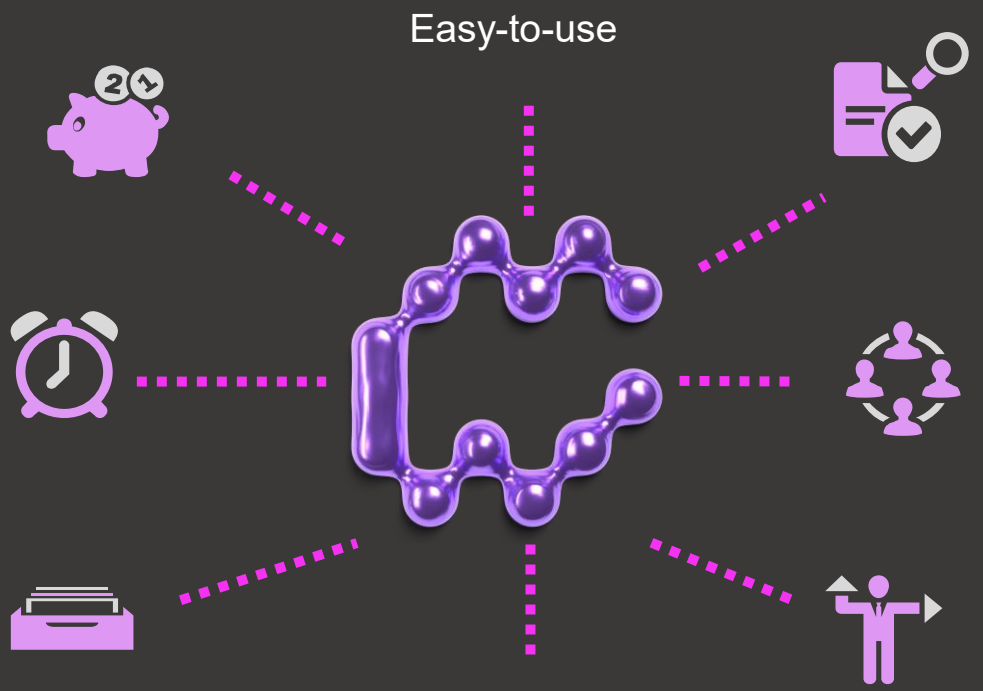
Core Elements of EASYCLIN®

Next level trials: STANDARDIZED and DIGITAL.

- Fixed affordable pricing
- Easy cancellation
- End-to-end trial process coverage
- No customising needed
- Study specific configuration tools
- Regulatory documentation



- All templates included
- Adaptable configuration tool included (validated)
- Pay-per-study
- unlimited number of users!
- Global feasibility network

- Made in UK Germany & Austria
- Expert consultancy

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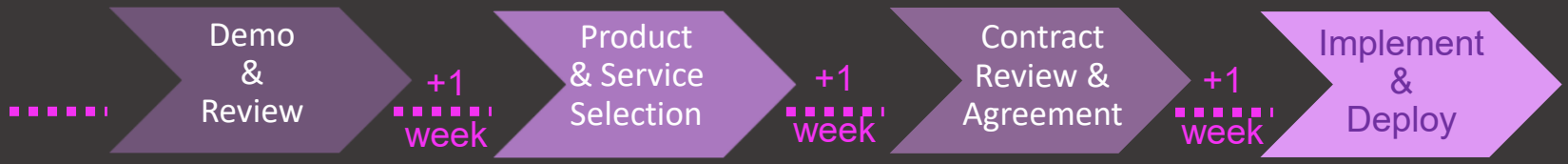
EASYCLIN® How to Start

Your onboarding process



- First contact with our product line
- Product presentation
- Online product demo / video

- Requirement analysis, ticketing according to e.g. funding requests
- OPTIONAL: 2 days of consulting and deep analysis

- Sign contract
- Pay startup fee
- Installation starts right away (fast-track)
- Master Service Agreement (contract) finalized in parallel

- System is being deployed, tested and validated
- Training session with the team
- Project starts
- Pay monthly fees

Fixed price concept, no fee per user, easily affordable for companies of all sizes, ROI less than 8 months.

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EASYCLIN® Start Up Options

Fast track or standard setup

FAST TRACK (start in 3 weeks)

- Setup starts immediately after full start-up fee is paid
- MSA master service agreement is provided in parallel
- Study can start immediately

STANDARD (start in 1-3 months)

- Only 50% starting fee upfront
- Finalization and execution of MSA
- Implementation process starts after second 50% fee is paid

ongoing service and support

Quality management included, unlimited users and countries

monthly payments start after the release

special startup conditions available on request: sales@synapcon.com

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EASYCLIN® Data Protection

A self-contained system – GDPR by design

EasyClin Compliance Overview

- **EU-GCPR Compliant**: Adheres to European Good Clinical Practice standards for clinical trials.
- **Rigorous Validation Programming**: Ensures quality and reliability through extensive testing.
  GDPR by Design: Data protection and privacy embedded in core architecture.
- **ISO 27001, ISO13485, ISO 14971, ISO 80002-2, IEC 62304**: Compliance with key ISO standards for security, risk management, and software lifecycle.
- **Client-Qualified GDPR Compliance:** EasyClin ’s EU-GDPR compliance was verified by our clients, ensuring secure and compliant data handling.

EASYCLIN® Cyber Security

Double encryption and robust authentication – Cybersecurity by Design

EasyClin aims to proactively protect patient data, clinical trial data, and maintain compliance with global cybersecurity requirements, ensuring the platform remains secure, resilient, and trustworthy for all users.

Threat Assessment and Mitigation: During the design and development phase, potential cybersecurity threats are identified, and mitigating measures are embedded into the system.

Data Encryption: All sensitive data is encrypted both in transit and at rest to prevent unauthorized access.
Access Control: Strict user role-based access ensures that only authorized personnel can access specific features and data.

Regular Security Audits: EasyClin is subjected to frequent security assessments and audits to ensure adherence to global standards like ISO/IEC 27001 and EU GDPR.

Incident Response Mechanism: The system includes an incident response plan to quickly detect, contain, and remediate security incidents.

Security Awareness: SynapCon helps to ensure that its users are well-informed of security best practices, which helps reduce risks related to human factors.

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EASYCLIN® Cyber Security and Data Protection

Hosting, Management and Aspects – Our Specialists

The Public Cloud Group (PCG) collaborates with SynapCon to manage their AWS cloud platform, designing and implementing a secure, stable AWS cloud environment tailored for SynapCon’s “EasyClin" software, which manages clinical study data (cloud platform development).

Providing ongoing support through services such as monitoring, incident management, backup and recovery, billing and security. These services ensure continuous, reliable operation of SynapCon's cloud infrastructure (managed services).

Ensuring the platform adheres to stringent security and compliance standards, including GDPR, to protect sensitive patient data (compliance and security)

This partnership enables SynapCon to offer its “EasyClin" software via a robust, compliant cloud platform, facilitating efficient and secure management of clinical trial data.

The service is also available on request for other platform providers such as Azure and for on-premises solutions.

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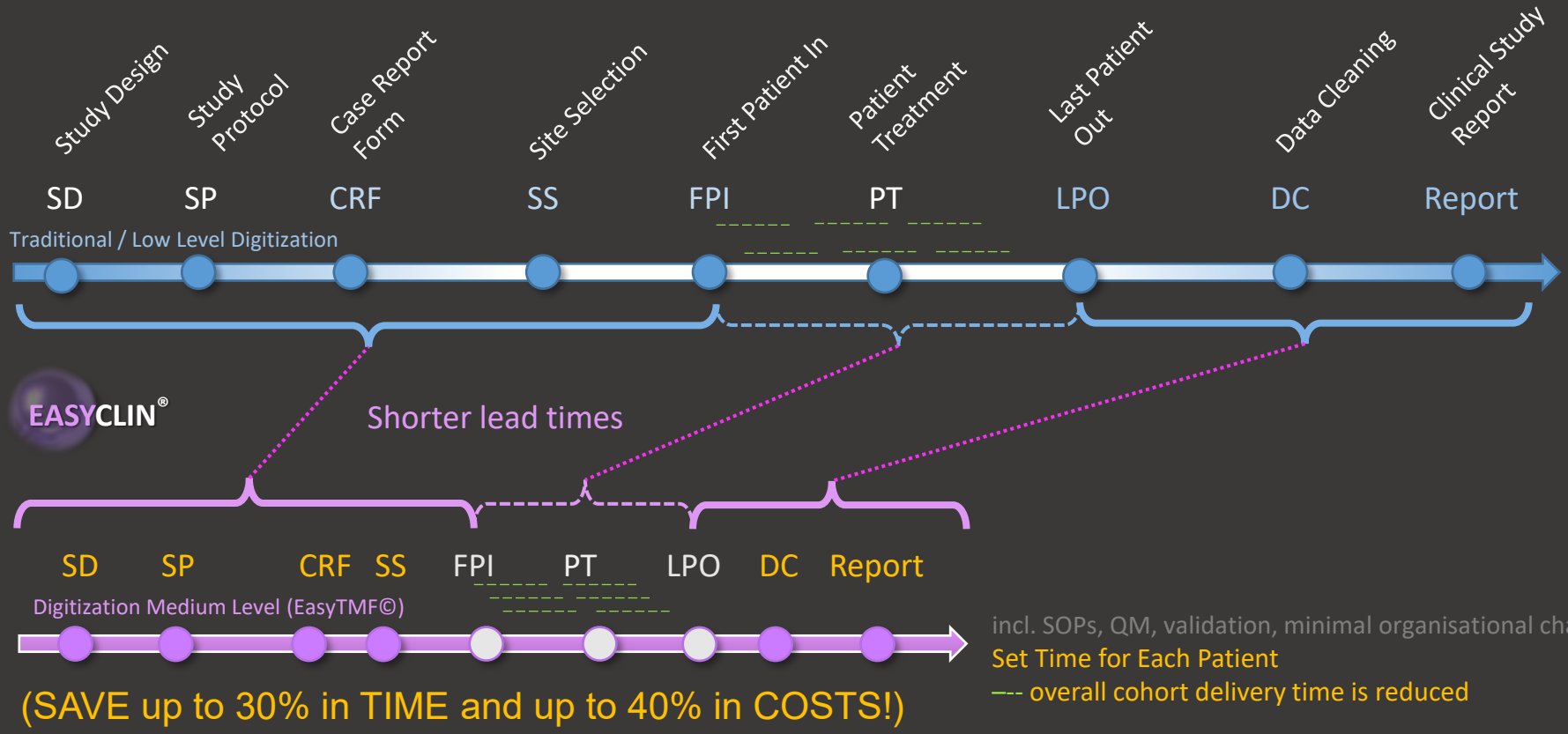
Key Points of a Study

Reducing clinical study time and costs

Conventional



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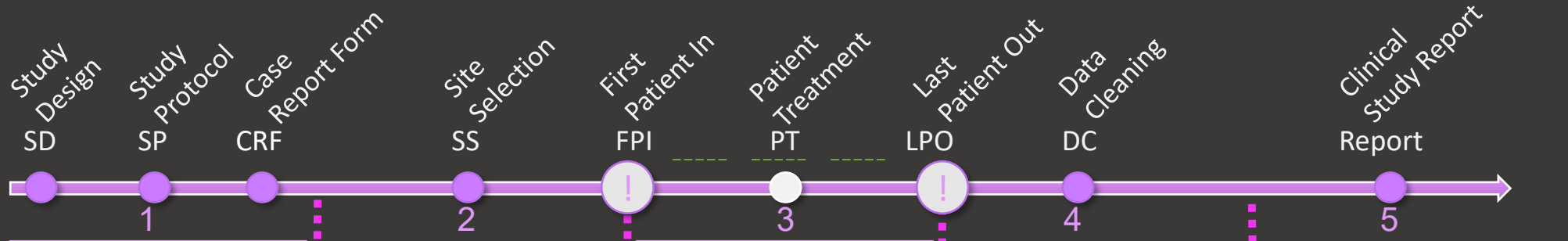
Key Values of EASYCLIN®

5 phases, 4 solutions to reduce time and cost



Study Design eCRF

- digital information
- documentation mgnt

➢ FAST, SAFE AND RELIABLE SETUP

➢ SAVE DURING PREPARATION

Savings

85 %* 80 %*

Site Selection eFEA

- improved site selection
- patient selection

➢ ACCESS CONTROL

➢ BETTER PATIENT SELECTION

➢ CLEAR, RELIABLE REPORTING

60 %* 45 %*

Treatment eTMF

- dashboard visibility
- error reduction

➢ REDUCED DELIVERY TIME

➢ REDUCED OVERHEADS

30-90 %* 10 %*

Reporting: eCLIN

- document cleaning,
- write access controls

➢ IMPROVED DATA ANALYSIS INPUTS

➢ INSPECTION-READY

75 %* 85 %*

Post Study eCLIN

- data freeze,
- “archive“ XML export

➢ ERROR-FREE SUBMISSIONs

➢ AUDIT PROOF ARCHIVING

90 %* 75 %*

INTEGRATED PROCESS AUTOMIZATION AND SURVEILLANCE

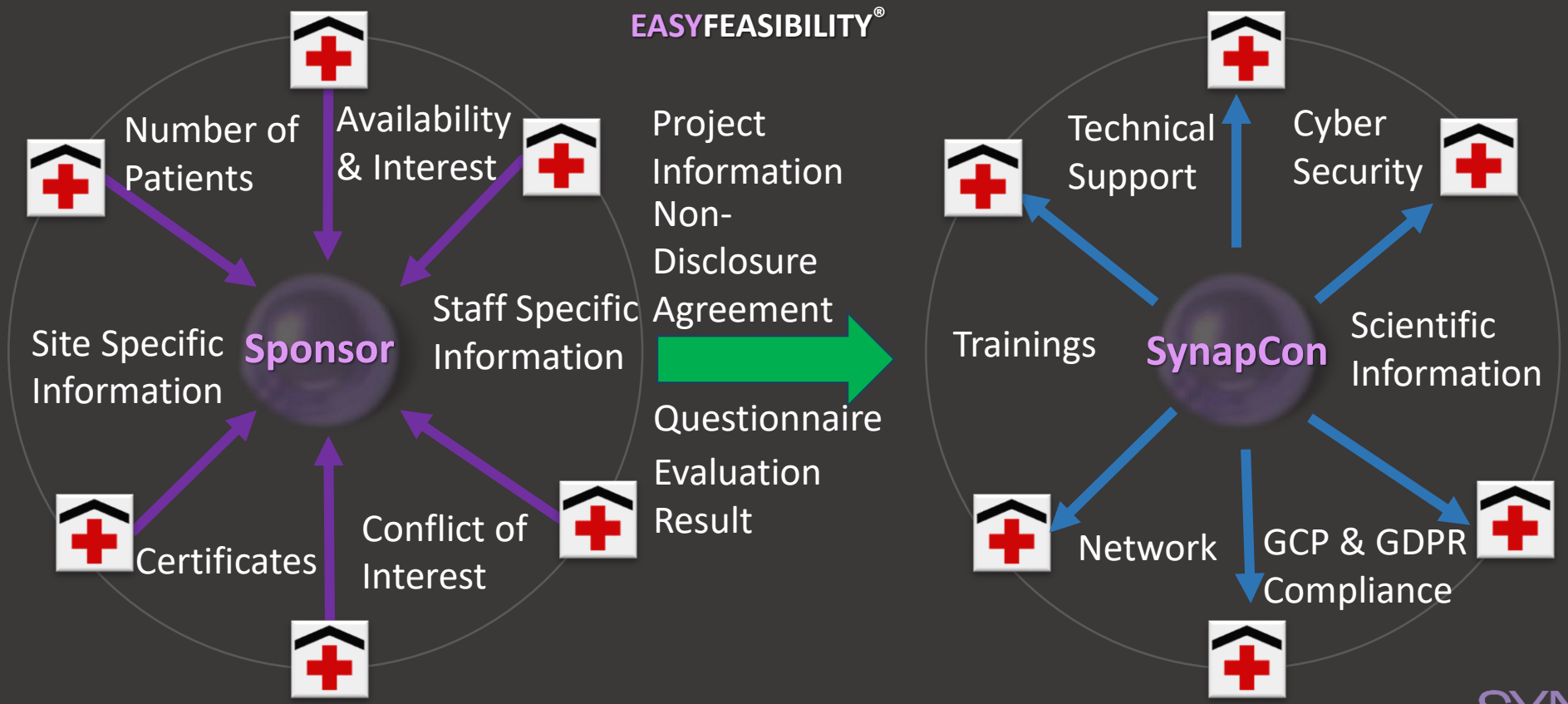
*estimated anticipated savings

SYNAPCON

EASYFEASIBILITY®

Site Identification, Feasibility and Selection

Distributes and collates essential documents for the evaluation of the study sites



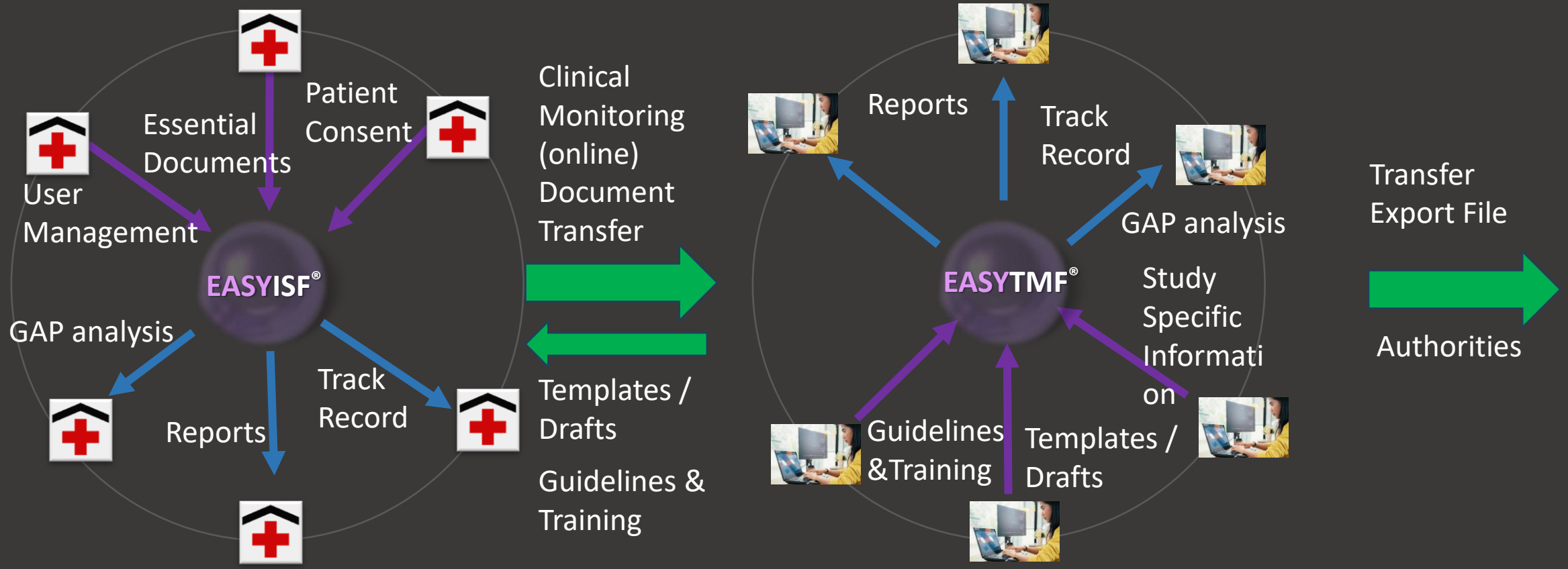
SYNAPCON

EASYISF®

EASYTMF®

Regulatory compliant document management and transfer

Distributes and collates and submission od essential documents before, during and after a clinical study

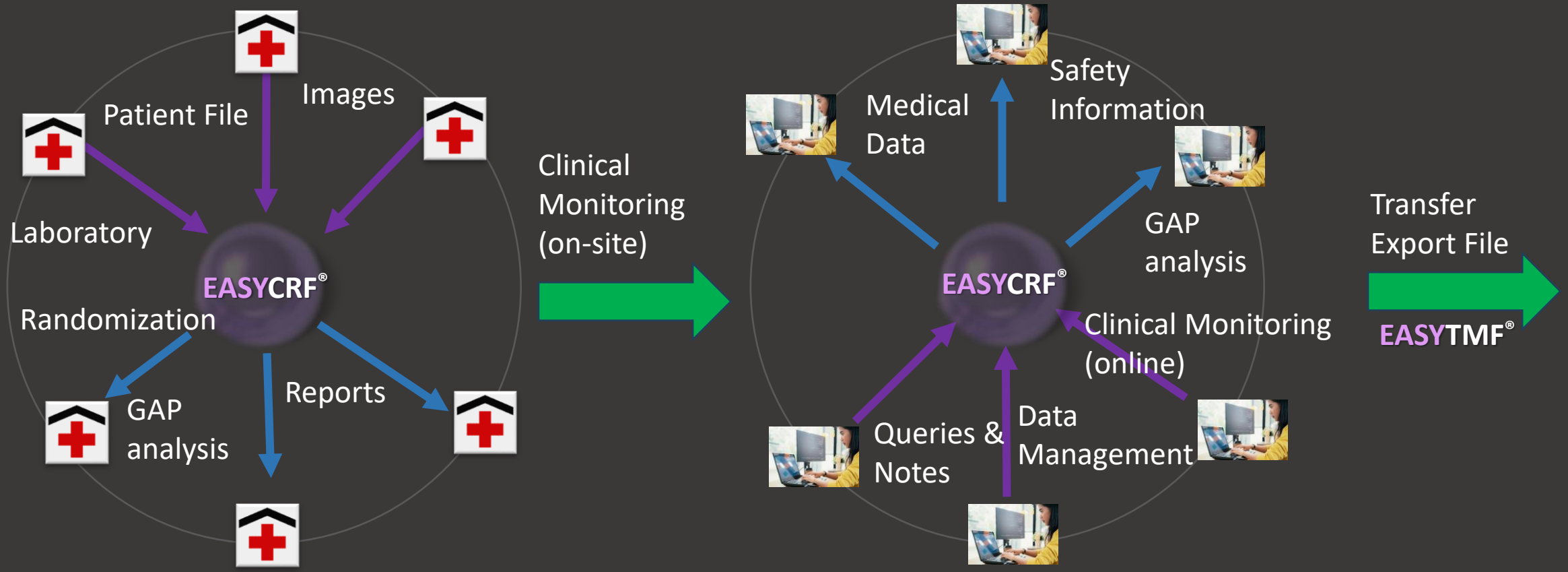


SYNAPCON

EASYCRF®

Regulatory compliant clinical data management

Collecting and monitoring medical data as part of a clinical research study



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SynapCon - the new digital standard in clinical trials

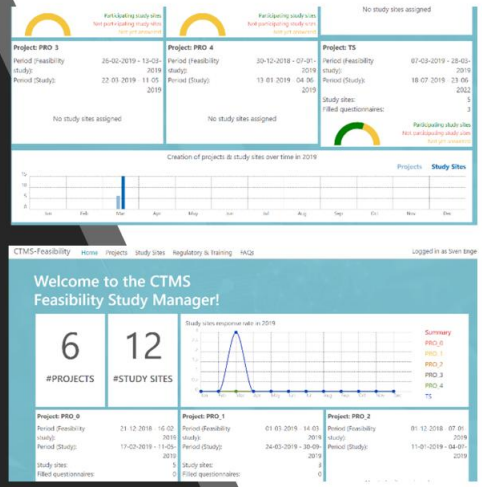
- Key Aspects and Core Values of SynapCon`s strategic approach -

EasyClin© – Product Line

EASYFEASIBILITY©

EU-GDPR conform site selection and documentation

- This complex but easy-to-use tool takes your professional and EU-GDPR compliant study site selection to a unique level and saves up to 80% of the costs compared to the standard
- EasyClin©feasibility is available globally at any time for a small user fee (registration is for free). The pricing follows the concept you may know from your Netflix, Amazon Prime or Apple Music account. This means in fact that you can login, register, activate and perform. Termination without further notice, just enjoy, riskless.



SynapCon - the new digital standard in clinical trials

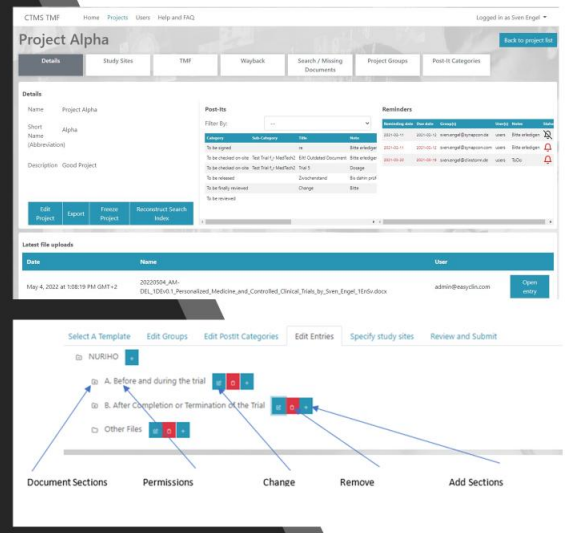
- Key Aspects and Core Values of SynapCon`s strategic approach -

EasyClin© – Product Line

EASYTMF©

Global clinical trial relevant documentation

- Beside the requested functions and features, using our CTM system provides advantages and sophisticated features to make your daily documentation and work easier. For example, the historical view (wayback function) post-it function supporting a multi-directional and pro-active management, as well as many more.



SynapCon - the new digital standard in clinical trials

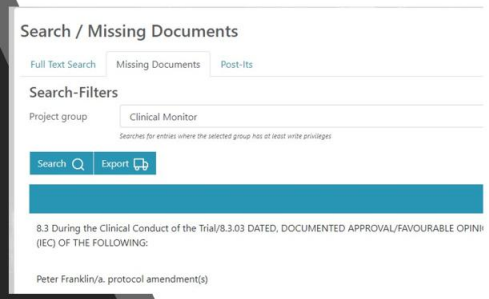
- Key Aspects and Core Values of SynapCon`s strategic approach -

EasyClin© – Product Line

EASYISF©

Site specific clinical trial relevant documentation

- The investigator/institution is responsible for the suitability of the investigator TMF (ISF). Regardless of what arrangements are put in place for an eTMF, these should ensure that this responsibility can be fulfilled and that the investigator/institution maintains continuous access to and control of the files and their documents.
- When a third-party eISF is used, there should be assurance that the investigator/institution can fulfil their responsibility" (ref. Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic), effective since June 2018, section 4.1.3).



SynapCon - the new digital standard in clinical trials

- Key Aspects and Core Values of SynapCon`s strategic approach -

EasyClin© – Product Line

EASYCRF©

ICH-GCP, GAMP5 and 21 CFR part 11 conform medical data collection

- Design and implementation of a case report form needs experience, as well as operational and technical knowledge
- We have developed a user friendly and cost-efficient solution to easily report all medical information from your investigational study sites.
- This eCRF solution is based on 30+ years of clinical operation experience
- Our eCRF includes a state-of-the-art tool for randomized trials, supportive functions to detect hidden events, as well as a deep learning mechanism to help you better analyze your medical data.
- SynapCon can offer a wide range of services to quickly create and use your eCRF.

What Others Say

Awards and customers

Best Clinical Trial Management System
by Clinical Trial Management System & GHP Clinical Research Innovation Excellence Award 2021 and 2023

Best Clinical Trial Management System Global
by M & A TODAY Global Awards 2022 and 2023

Best Clinical Research Software Distributor 2022
by GHP Private Healthcare Awards 2022

Best Biotech Development Software Germany 2023
by Corporate Live Wire Global Awards 2022

Best Employer of the future 2023
by DVAG Deutsche Vermögensberatung

Best Clinical Development Solutions Company 2023
by International Life Sciences Global Awards 2022/23

Best Clinical Trial & Medical Research Software Solutions Company 2024 – Europe

by Corporate Vision – Corporate Excellence Awards

Best Pharma & BioTech Clinical Trials Digitisation Company 2024

GHP BioTech Innovation Excellence Award 2024

by GHP Biotechnology Awards 2024

Best Clinical Trial Management System UK 2025
by M & A TODAY Global Awards 2025

„The price-performance ratio in combination with the regulatory expertise is convincing.“

Global medical device producer ophthalmology
EasyTMF® Vendor Qualified (GAMP5_second edition)

„The technical and regulatory expertise of SynapCon is outstanding.“

Start-up medical device producer wound care

“The ease of use, functionality and transparency of EasyTMF(r) keeps us competitive”.
Leading European CRO in the field of regulatory affairs, clinical studies P II-IV, NIS and PMS
EasyTMF® Vendor Qualified (GAMP5_second edition)

SYNAPCON

100% Satisfaction

AUDIT PROOF

QUALIFIED VENDOR 2023,2024, 2025

Even for governments.

Federal Ministry of Education and Research

Federal Ministry for Economic Affairs and Energy

Horizon 2020 European Union Funding for Research & Innovation

100% regulatory conform with FDA, EMA, GAMP5, ICH-GCP, 21 CFR pt.11, NHS DTAC

30+ years of expertise

250+ studies performed

Granted and officially supported by the EU and the two main German Ministries.

SYNAPCON

2025: Distributed Ledger Technology
2026: Adding AI (Artificial Intelligence)

Integrating Machine Learning (ML) and Blockchain Technology (BT)

Blockchain Technology (BT):

- enhance data integrity through distributed ledger technology
- verify and validate
  - ✓ identities and sources
  - ✓ documents and signatures
  - ✓ medical data and images
  - ✓ trial processes and workflow

Machine Learning by AI:

- enable access to clinical patient data points (blood tests, MRI scans), combine, compile and recombine for new settings
- incentivize the clinical sites or patients (wearables!) to provide the critical data, providing them with the major revenues associated
- access to patient data points from the various sites (global portal)
- delivering answers through big data analyses via bayesian statistics

SYNAPCON

Contact Us:

Ask for a consultation and demonstration

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Live Demonstration: https://calendly.com/sven-engel-1

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