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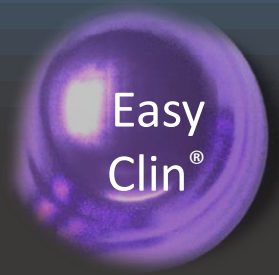
Digital Clinical Trials



STANDARDIZED – EASY TO USE – AFFORDABLE

The control center for clinical trials

March 2023

Nearly 50%

of all clinical trials are still paper-based.*

So we standardized the process.

(by writing a little software)

*www.veristat.com/sqn-blog/why-paper-trials

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After 20 Years of experience, we recognized:

A simplified Clinical Trial Management System (CTMS),
with its focus on the Trial Master File (TMF),
compiling all the information for the final processing,
is the nucleus of each clinical research project.

(Sven Engel, CEO SynapCon)

Let´s dive in.

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Why Ask Us?

➡ ”5P”

Proper

Pre-flight

Preparation

Prevents

Problems

Easy Clin®

Works both for clinical trials and helicopter crews...

Please speak to us early enough!

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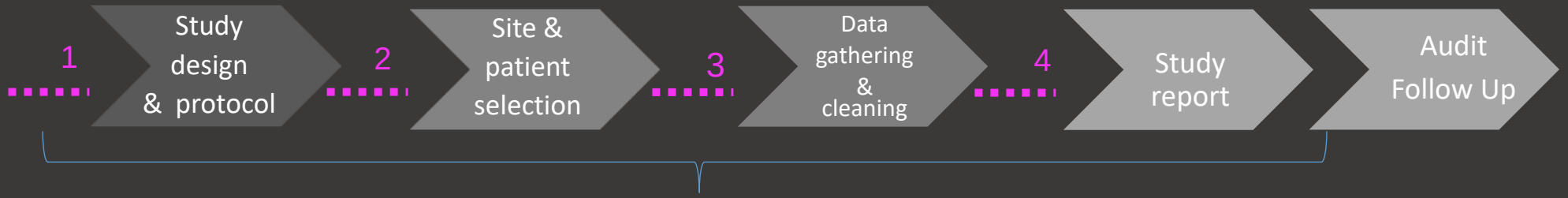
Why Use a CTMS?

Clinical trials are a complex, 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

Easy CLIN©

Control and fulfill your milestones!

The control center for clinical trials.

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EasyClin® - the Control Center

Easy. Affordable. Safe and compliant.

We offer a full coverage end-to-end software suite for your clinical trials.

- ✓ easy implementation
- ✓ easy training
- ✓ easy deployment & use
- ✓ easy extension & growth
- ✓ easy maintenance
- ✓ easy payments
- ✓ easy cancellation

- ✓ Inspection-ready
- ✓ Full oversight, realtime access
- ✓ Including all regulatory documentation and support

aids compliance with all main regulations:

- ✓ FDA
- ✓ EMA
- ✓ GDPR
- ✓ GAMP-5
- ✓ ICH-GCP
- ✓ ISO 9001
- ✓ ISO 13485
- ✓ ISO 14001
- ✓ 21 CFR pt.11
- ✓ NHS / DTAC

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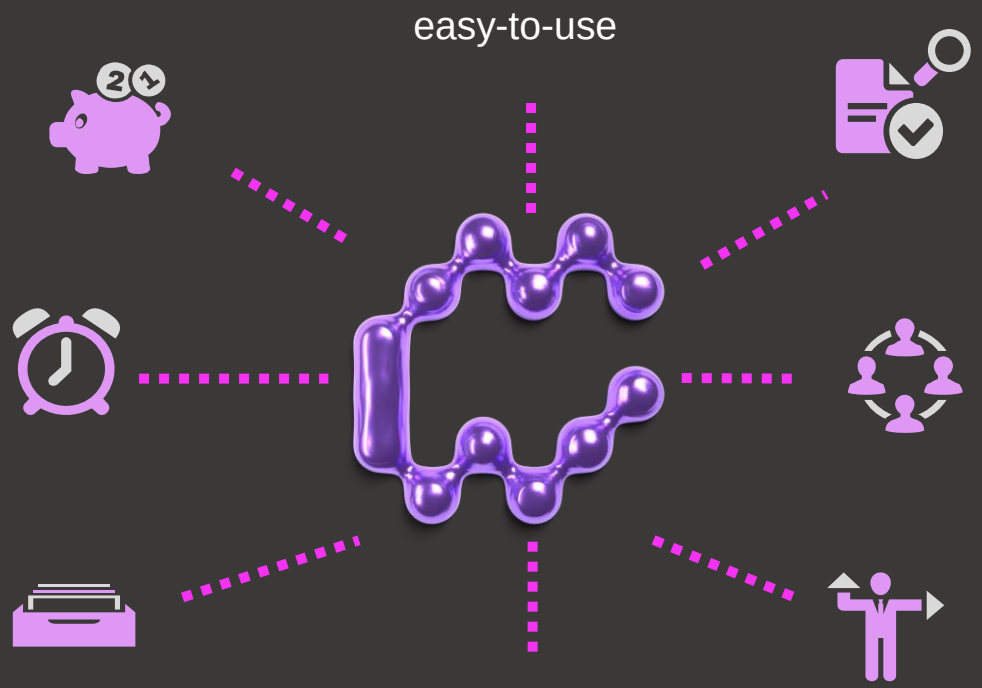
Core Elements of EasyClin®

Next level trials: STANDARDIZED and DIGITAL.

- affordable pricing
- easy cancellation
- end-to-end trial process coverage
- no customising needed
- study specific configuration tools
- regulatory documentation



- made in Germany
- expert consultancy

- all templates included
- adaptable configuration tool included (validated)
- pay-per-study
- unlimited number of users!
- global feasibility network

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EasyClin® - Documentation

All regulatory documentation included

Our software comes with all the contract work
and supporting documents needed for submission to authorities:

✓	contract package	(MSA, etc.)
✓	training package	(training)
✓	SOP´s	(customer specific is optional)
✓	additional validation material	(if applicable)
✓	customer related validation material	(if applicable)
✓	manuals and supporting documentation	
✓	easy cancellation	(if applicable)

A full set of documentation will be delivered
while setting up the system, after signing the agreements.

NO EXTRA FEES!

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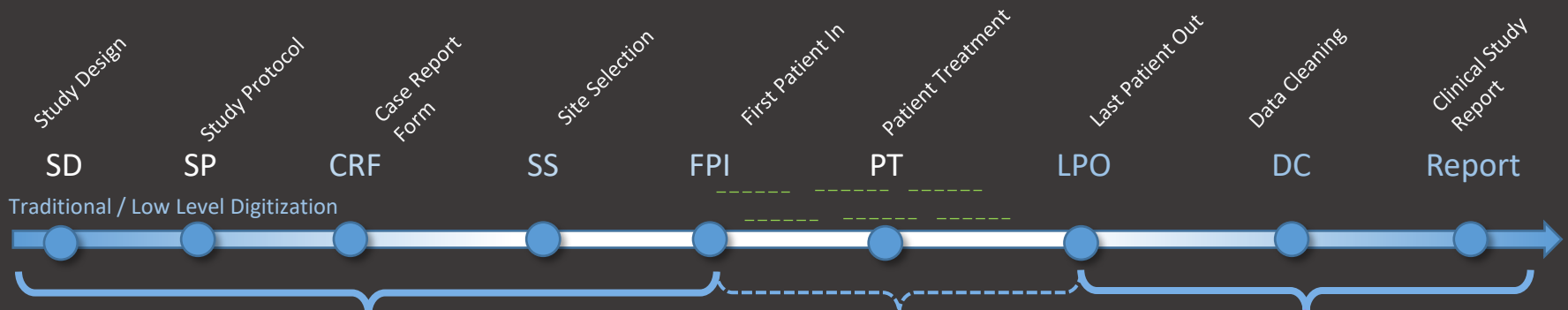
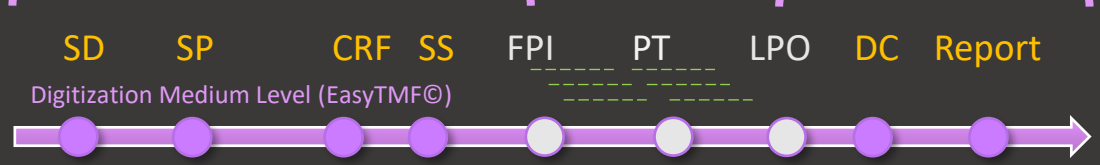
Key Points of a Study

Where exactly do we come in (from design to report)?



Easy TMF©

Shorter lead times



(SAVE up to -30% in TIME and up to -40% in COSTS!)

incl. SOPs, QM, validation, minimal organisational changes

Set Time for Each Patient

–– overall cohort delivery time is reduced

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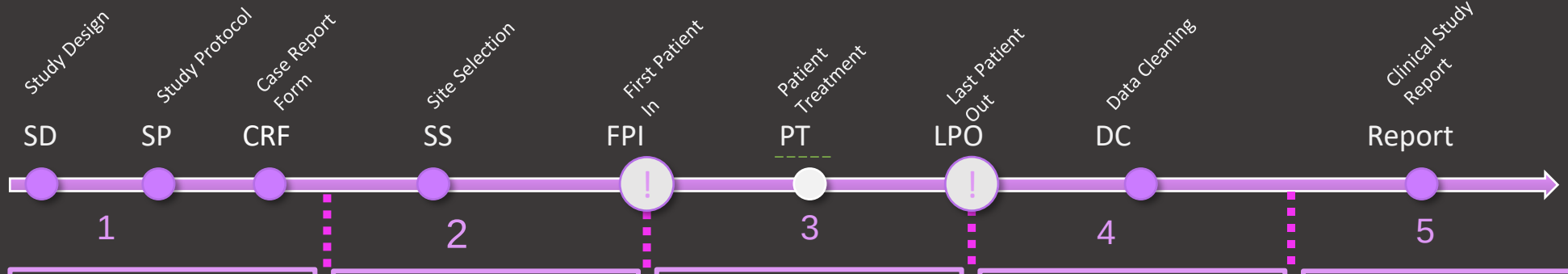
Key Values of EasyClin®

4 phases of solutions and benefits



#1 – Study Design, Protocol & CRF:

digital information and documentation management
Savings time, cost

- FAST, SAFE AND RELIABLE SETUP
- SAVE DURING PREPARATION

#2 - Study Site Selection (eFEA):

better, faster site and patient selection

Savings time, cost

- ACCESS CONTROL
- BETTER PATIENT SELECTION
- CLEAR, RELIABLE REPORTING

#3 Patient Treatment:

error-minimizing dashboard visibility of progress, informing delivery

- REDUCED DELIVERY TIME
- REDUCED OVERHEADS

#4 - Data Cleaning & Data Report:

document cleaning, error-minimizing dashboard control, revocation of write access rights

- IMPROVED DATA ANALYSIS INPUTS
- INSPECTION-READY

#5 - After Study ends:

data freeze, “archive“ button (XML export)

- ERROR-FREE SUBMISSION TO AUTHORITIES
- SAVE ON POST PROCESSING
- AUDIT PROOF ARCHIVING

INTEGRATED PROCESS AUTOMIZATION AND SURVEILLANCE

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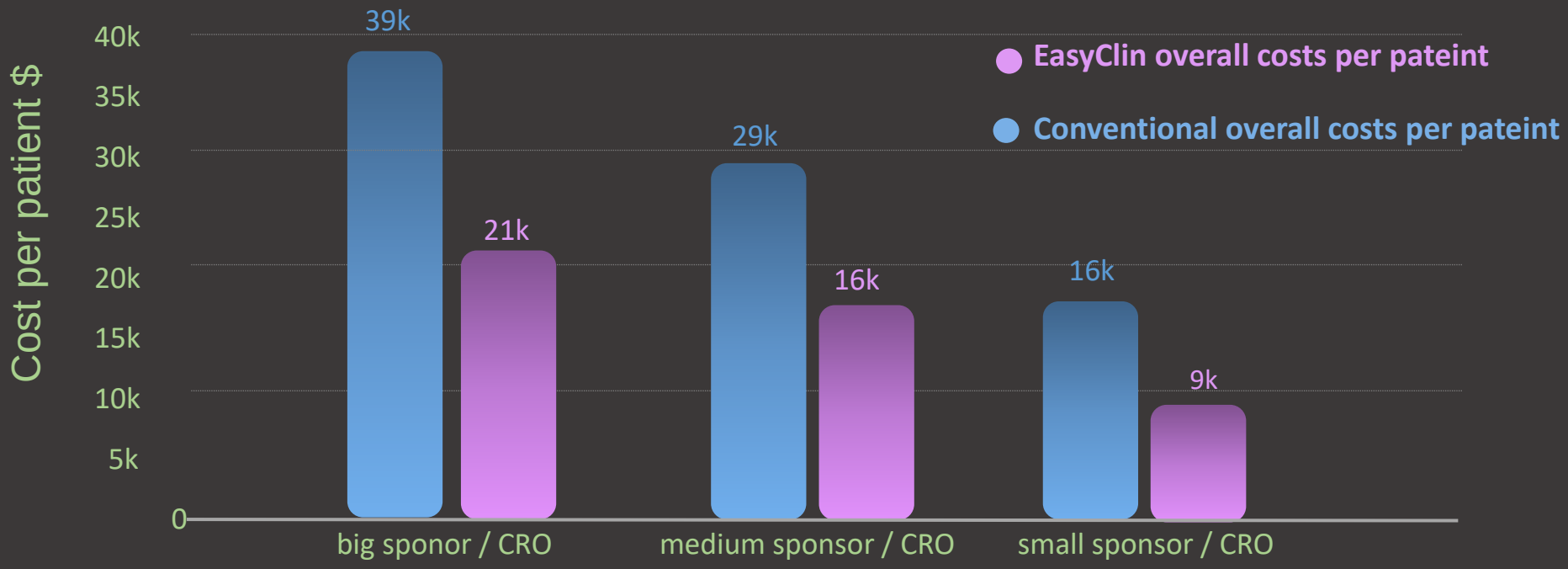
EasyClin® - Example Calculation

How much could you possibly save?

Comparative Relative Use Case:
Typical spending & savings per patient:



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EasyTMF® – our electronic TMF

Clinical trial file management & eTMF submission

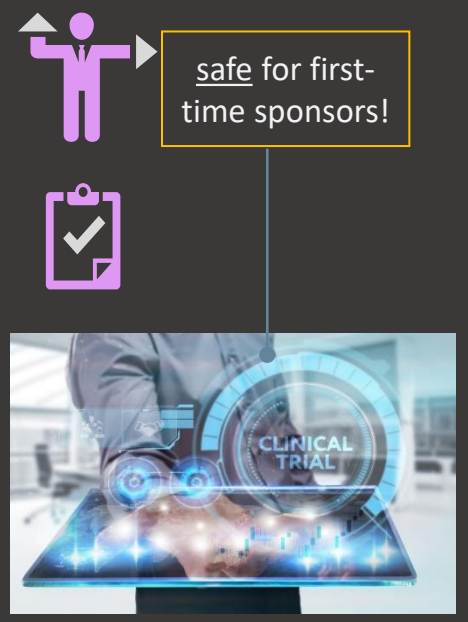
Value Proposition

- ✓ **Error-minimizing** via intuitive template structure, item naming
- ✓ **Easy-to-use** for all stakeholders
- ✓ **Effective risk management** via integrated audit trail navigation and upfront regulatory training
- ✓ **Time reduction for all participants** in search, editing assembly of docs + quick-finding of historic events
- ✓ **Investigator Site File (ISF) reconciliation option**

Product Purpose

Web-based platform leading all participants to systematically prepare and complete an audit-proof GCP-compliant trial master file

- ✓ Assemble data into compliant template structure
- ✓ Collaborate virtually into one integrated result
- ✓ Automatic storage of full history
- ✓ Easy date and object-related navigation



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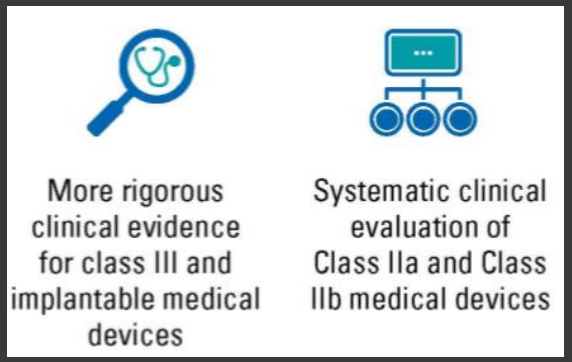
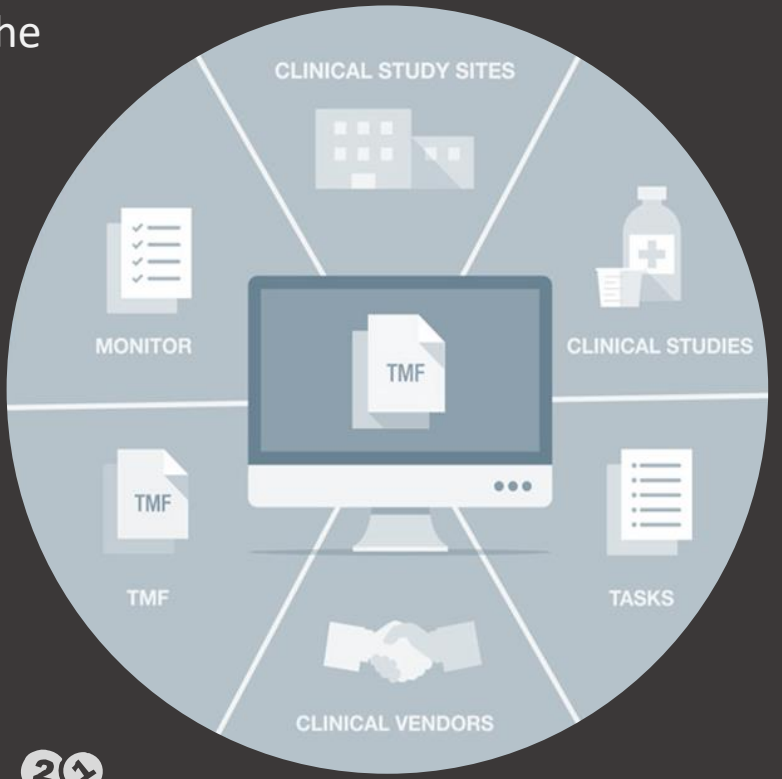
EasyTMF®

The Trial Master File (TMF) contains all essential documents that individually and collectively permit the evaluation of the conduct of a trial and the quality of the data produced.

source: ICH-GCP Chapter 8



source: TÜV Süd



We provide small and medium sized CROs, MedTech and Biotech companies with the technology of the big players at an affordable price.

source: Sven Engel, founder SynapCon

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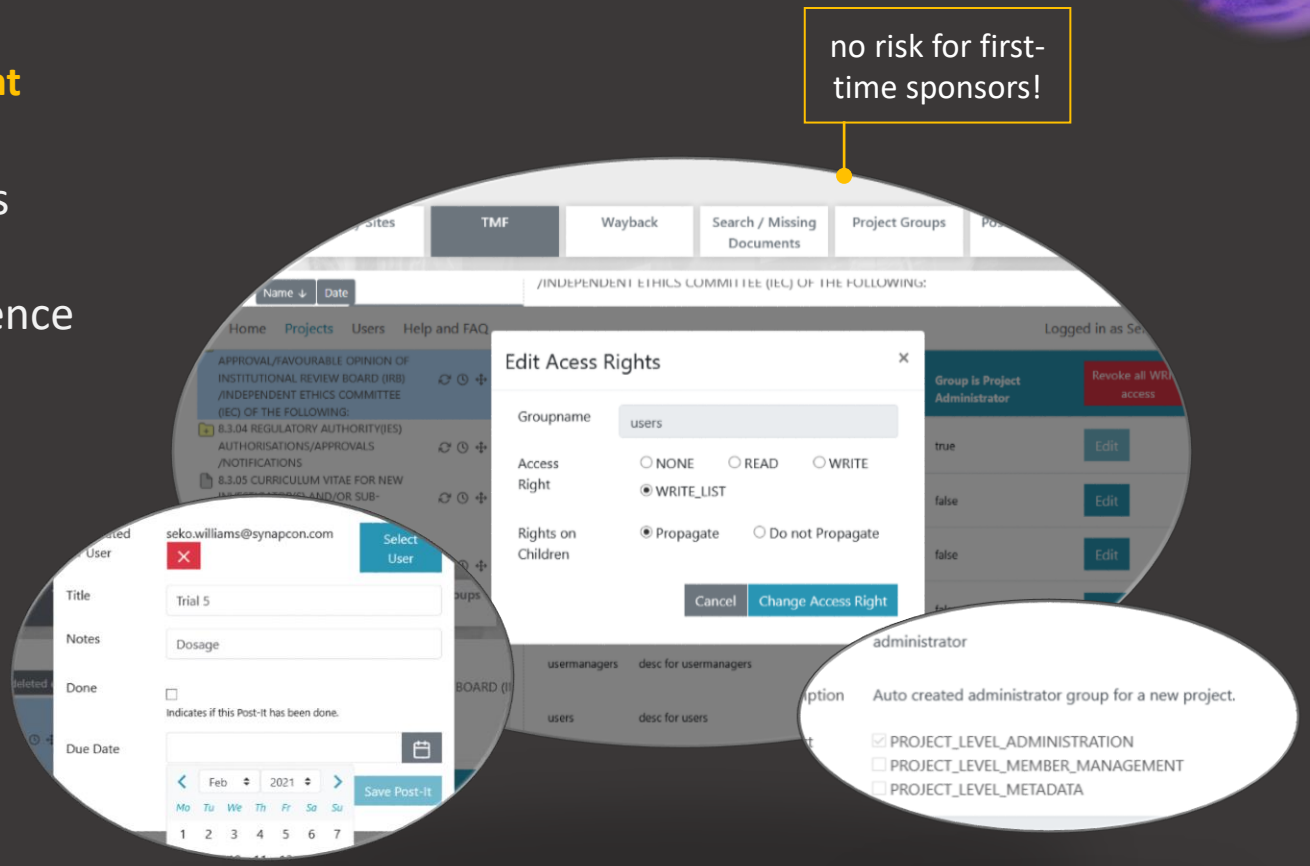
EasyTMF®

eTMF **User Management**

Challenge: Different users have different levels of responsibility and experience



Our eTMF provides a systematic and well-controlled user management down to doc level

→ reduced risk to corrupt data and files

→ reduced errors → faster and safer submission

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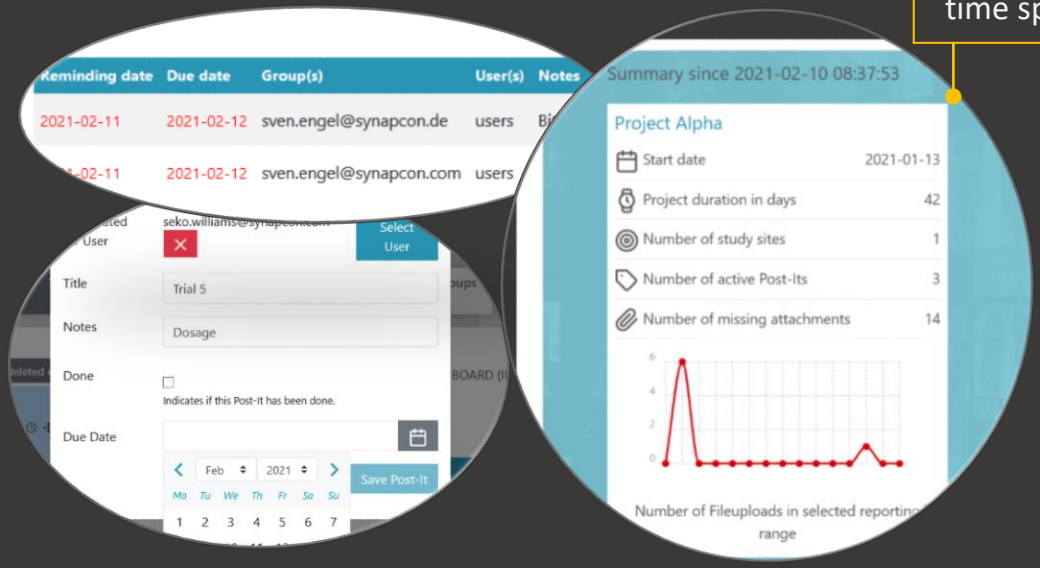
EasyTMF®

eTMF **Progress Report** and Project Management

Challenge: How to track progress to effectively manage projects while virtually working on various data and documents?



on-time for first-time sponsors!

Our eTMF provides intuitive progress report and project management support functions

→ On-time delivery and submission of the eTMF

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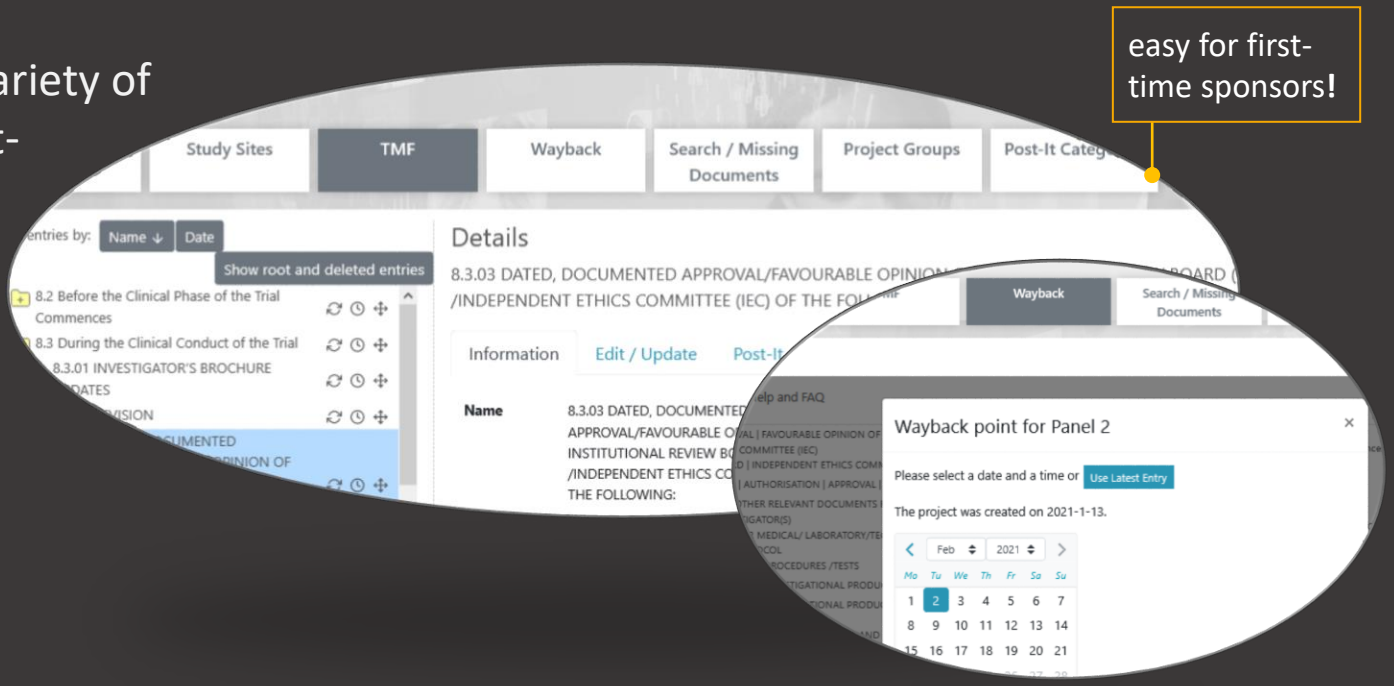
EasyTMF®

eTMF Navigation incl. **“Wayback“ and ISO conforming document naming**

Challenge: How do you integrate data and documents from a variety of sources into an audit-compliant TMF.



Our eTMF provides a virtual platform with easy-to-navigate files and history structures.

→ Reduced time to achieve an audit-proof TMF

→ Effective risk management → pass the audit

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Supporting Products

Everything you need:

Preparatory work

Digital ready health check, study design, protocol support, study set-up, eCRF (optional), embedded technology, advisory board, data monitoring committee

Feasibility portal: Study site selection

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

Investigator study file

Realtime tracking, KPI and risk metrics

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2023 / 2024: Adding AI (Artificial Intelligence)

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

Blockchain Technology (BT):

- verify and validate

✓ Indenties

✓ Patient documents

✓ Clinical data

✓ Trial processes

Machine Learning (ML, fully automized):

- 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)

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What Others Say

Awards and customers

Awards :

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

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

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

Best Biotech Development Software Germany 2023
by Corporate LiveWire Global Awards 2022

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

Dr. Norbert Clemens, Director Clinical Trial Management EMEA at HOYA Surgical Optics GmbH

HOYA SURGICAL OPTICS

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

Dr. Carsten Mahrenholz, Founder & CEO of COLDPLASMATECH GmbH

COLDPLASMATECH

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100% Satisfying

Even for governments.

QUALIFIED VENDOR 2023

AUDIT PROOF

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*

* Operations and IT

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

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Contact Us:

Ask for a consultation and demonstration

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