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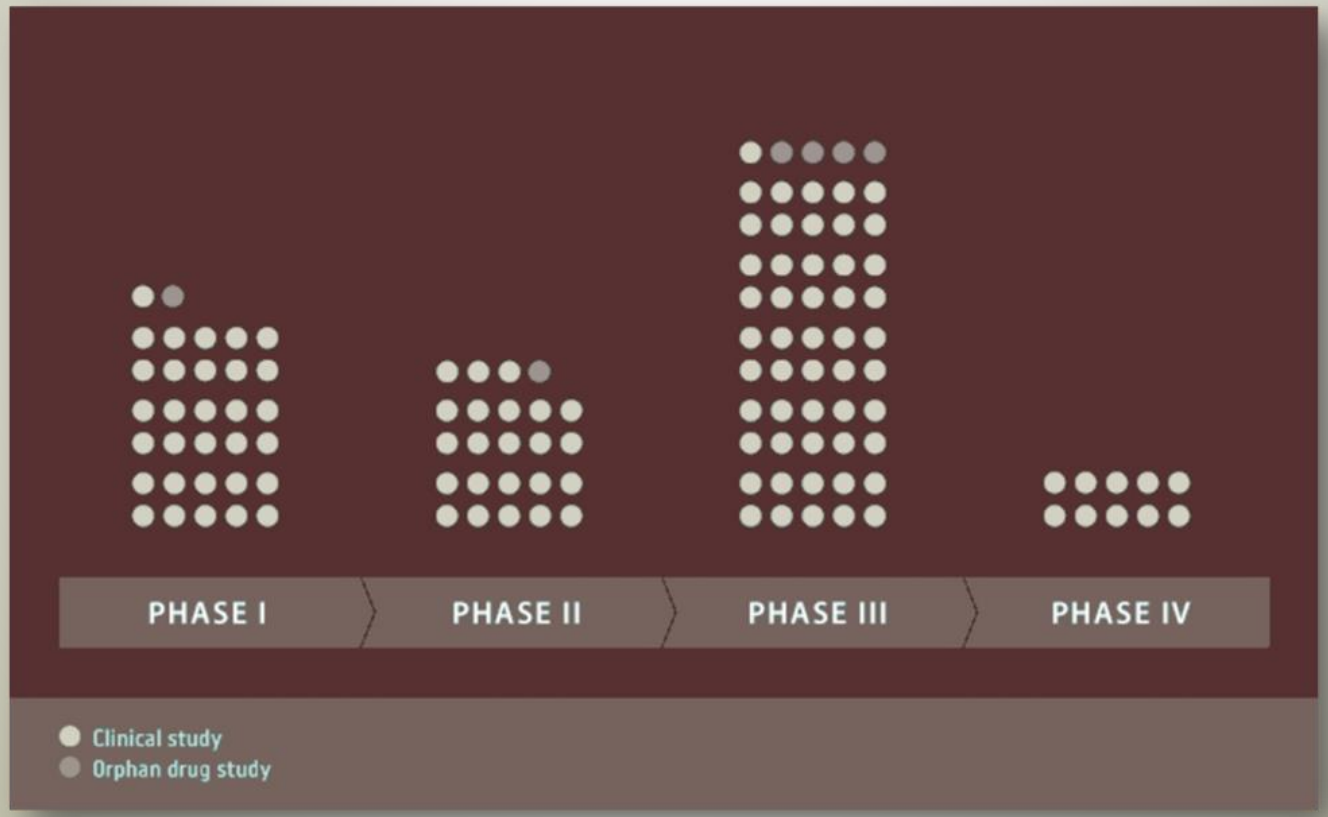
Your best choice
to get your substance ready for the market!

Mission

Sacura is a **full-service** contract research organization granting a **high level of quality, flexible structures and qualified staff**.

We are dedicated to the success of our clients by providing extensive support through a network of experienced **seasoned consultants in leading positions** from the international Big Pharma industry to cover the entire product life cycle process.

Clinical Trials in all Phases



International Phase I Studies, First in Man

- Pharmacokinetics and Pharmacodynamics
- Genotyping
- Food interactions
- Coagulation factors
- Renal impairment

International Phase II – IV Studies

Anti-infective drugs
- Quinolones (Gyrase Inhibitors)
- Cephalosporins
- Macrolides

Skin and subcutaneous tissue disorders
- Onychomycosis
- Brittle nail syndrome
- Psoriasis

Respiratory disorders
- Acute asthma
- COPD
- ILD
- Exacerbation of chronic bronchitis and acute bronchitis (Paediatrics)
- Pneumonia
- Maxillary sinusitis

Infections
- Influenza (Vaccination)
- H5N1 (Vaccination)
- HIV
- Sepsis

Blood and lymphatic system disorders
- Tonsillitis

Ear and labyrinth disorders
- Otitis media
- Acute tinnitus

Endocrine, Metabolic and Nutrition disorders
- Diabetes mellitus type I/II
- Impaired glucose tolerance
- Hypercholesterolemia
- Partial androgen deficiency of aging males (PADAM)
- Dyslipidaemia (primary/mixed) - Frederickson Types IIa & IIb
- Low HDLc

continued …

Gastrointestinal disorders
- Irritable bowel disease
- Morbus Crohn
- Gastro esophageal reflux disease (GERD)
- Mucositis in children and adults undergoing stem cell transplantation

Cardio and cardiovascular diseases
- Coronary heart disease
- Hypertension

Renal and urinary tract diseases
- Pyelonephritis
- Urinary tract infection
- Stress urinary incontinence
- Mixed urinary incontinence
- Overactive bladder
- Renal impairment

Reproductive system and breast disorders
- Dysfunctional uterine bleeding
- Endometriosis
- Erectile dysfunction
- Premature ejaculation
- Benign prostate hyperplasia

Musculosketal and bone diseases
- Rheumatoid arthritis
- Osteoarthritis of the knee
- Postmenopausal osteoporosis

Nerve system disorders
- Vascular dementia
- Alzheimer's disease
- Post herpetic neuralgia
- Painful diabetic neuropathia
- Restless legs syndrome
- Chronic non-malignant pain
- Multiple sclerosis
- Spinal cord injury

Psychiatric disorders
- Schizophrenia

continued …

Tumor diseases
- Breast cancer
- AML
- CLL
- SCLC
- Osteosarcoma
- Metastatic epithelial tumor cells diagnostic in mamma and colon carcinoma patients

Congenital, familial and genetic disorders
- Amyloidosis (Familiar amyloid polyneuropathia, FAP)
- Hereditary angioedema

Immune system disorders
- Neutropenia

Pediatric diseases
- Neonatology

Other
- Parenteral nutrition
- Vitamin C
- Radiographic contrast media
- Medical devices

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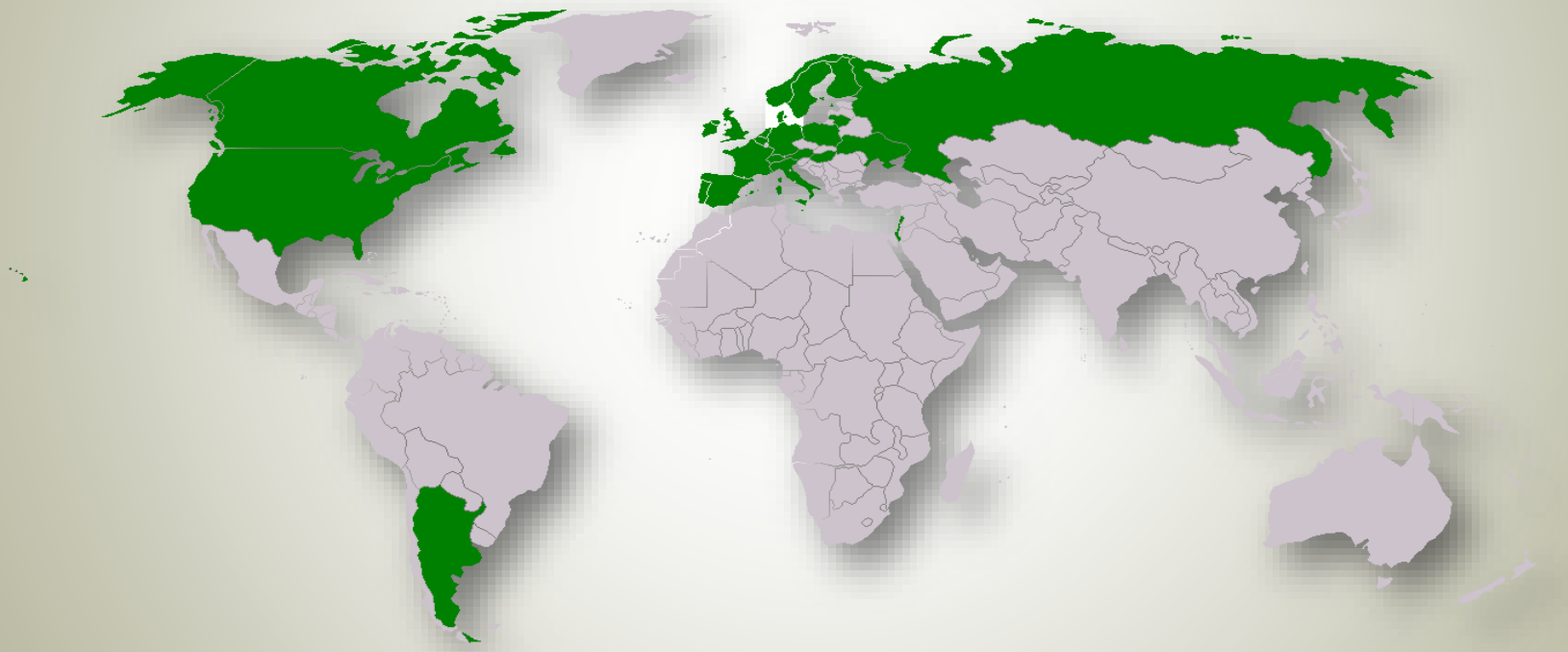
Regions of Activity



Regulations and Laws

Examples for the German legal jurisdiction

Common Regulations

- WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
- ICH Topic E6 Guideline for Good Clinical Practice (CPMP/ICH/135/95)
- Verordnung zur Änderung strahlenschutzrechtlicher Verordnungen
- Strahlenschutzverordnung - StrlSchV
- Röntgenverordnung - Röv
- Gesetz zur Änderung des Bundesdatenschutzgesetzes und anderer Gesetze

Continued …

Pharmaceuticals

- EMA – Aktualisierte Leitlinie für Arzneimittel mit modifizierter Wirkstoffabgabe
- Regulatory information - EMA releases practical guidance on access-todocuments requests
- EMA – Aktualisierte Leitlinie über das Qualifizierungsverfahren für neue Methoden in der Arzneimittelentwicklung
- Neue EU-Verordnung Nr. 536/2014
- 2. Gesetz zur Änderung arzneimittelrechtlicher und anderer Vorschriften (19.10.2012, 16. AMG-Novelle)
- Richtlinie 2009/120/EG der Europäischen Kommission Änderung der Richtlinie 2001/83/EG zur Schaffung eines Gemeinschaftskodexes für Humanarzneimittel im Hinblick auf Arzneimittel für neuartige Therapien
- 15. AMG Novelle - Gesetz zur Änderung des AMG
- Richtlinie 2005/28/EG der Kommission "The GCP Directive"
- GCP-V - Verordnung über die Anwendung der Guten klinischen Praxis bei der Durchführung von klinischen Prüfungen am Menschen
- Richtlinie 2003/94/EG der Europäischen Kommission
- Festlegung der Grundsätze und Leitlinien der Guten Herstellungspraxis für Humanarzneimittel und zur Anwendung beim Menschen bestimmte Prüfpräparate vom 08.10.2003 (ABl. L 262 vom 14.10.2003, S. 22)
- Richtlinie 2001/83/EG des Europäischen Parlaments und des Rates
- Richtlinie 2001/20/EG des Europäischen Parlaments und des Rates "The Clinical Trials Directive"
- Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz - AMG)
- Verordnung Nr. 1901/2006 über Kinderarzneimittel
- zur Änderung der Verordnung (EWG) Nr. 1768/92, der Richtlinien 2001/20/EG und 2001/83/EG sowie der Verordnung (EG) Nr. 726/2004
- Entwurf eines Gesetzes zur Änderung arzneimittelrechtlicher und anderer Vorschriften

Continued …

Medical Devices

- MPG - Medizinproduktegesetz
- Verordnung über klinische Prüfungen von Medizinprodukten (MPKPV) vom 10. Mai 2010 (BGBl. I S. 555)
- Medizinprodukte-Sicherheitsplanverordnung - MPSV
- Erfassung, Bewertung und Abwehr von Risiken bei Medizinprodukten
- Gesetz zur Änderung medizinprodukterechtlicher Vorschriften (vom 29. Juli 2009)
- Verordnung über das datenbankgestützte Informationssystem über Medizinprodukte
- des Deutschen Instituts für Medizinische Dokumentation und Information (DIMDI)
- DIN EN ISO 14155 Klinische Prüfung von Medizinprodukten an Menschen
- Gute klinische Praxis (DIN EN ISO 14155:2011 + AC:2011)
- Medical Devices - Richtlinien der Europäischen Kommission
- Die folgenden Richtlinien sind immer in Verbindung mit den nationalen Bestimmungen zu betrachten, da viele Ausnahmeregelungen bestehen.
- EU-Regulatory Framework
- Revision of the Regulatory Framework for Medical Devices
- The EU regulatory framework actually consists of Directive 93/42/EEC for Medical Devices (MDD), Directive 90/385/EEC for implantable medical devices including AIMDs and Directive 98/79/EC for IVDs.
- Richtlinie 93/42/EWG - Medizinprodukterichtlinie
- Richtlinie 90/385/EWG, Angleichung der Rechtsvorschriften der Mitgliedstaaten über aktive implantierbare medizinische Geräte
- Richtline 98/79/EG - In-vitro Diagnostic Directive (IVDD)

Continued …

Advanced Therapies ATMP

- Richtlinie 2009/120/EG zur Anpassung von Richtlinie 2001/83/EG
- Verordnung Nr. 1394/2007 über Arzneimittel für neuartige Therapien zur Änderung der Richtlinie 2001/83/EC und Verordnung (EG) Nr. 726/2004
- Detailed Guidelines on GCP specific to ATMP, Detailed Guidelines on Good Clinical Practice specific to Advanced Therapy Medicinal Products (03/12/2009, ENTR/F/2/SF/dn D(2009) 35810).

Adverse Events, Safety Reporting

- Communication from the Commission, Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3'), 11.6.2011 (2011/C 172/01)
- ICH guideline E2F Note for guidance on development safety update reports, Step 4, September 2010, EMA/CHMP/ICH/309348/2008
- European database of Suspected Unexpected Serious Adverse Events, Eudravigilance – Clinical Trial Module, ENTR/CT4, April 2004
- AMG-AV (AMG-Anzeigenverordnung) vom 30. Oktober 2005, Verordnung über die elektronische Anzeige von Nebenwirkungen bei Arzneimitteln

DOKUMENTATION AND REPORTING

Clinical Trials Documentation

may be audited, inspected and approved by

- Local authorities
- Competent authorities
- Ethics committees
- Institutional Review Boards
- and the Sponsor of the study

in every of the participating countries

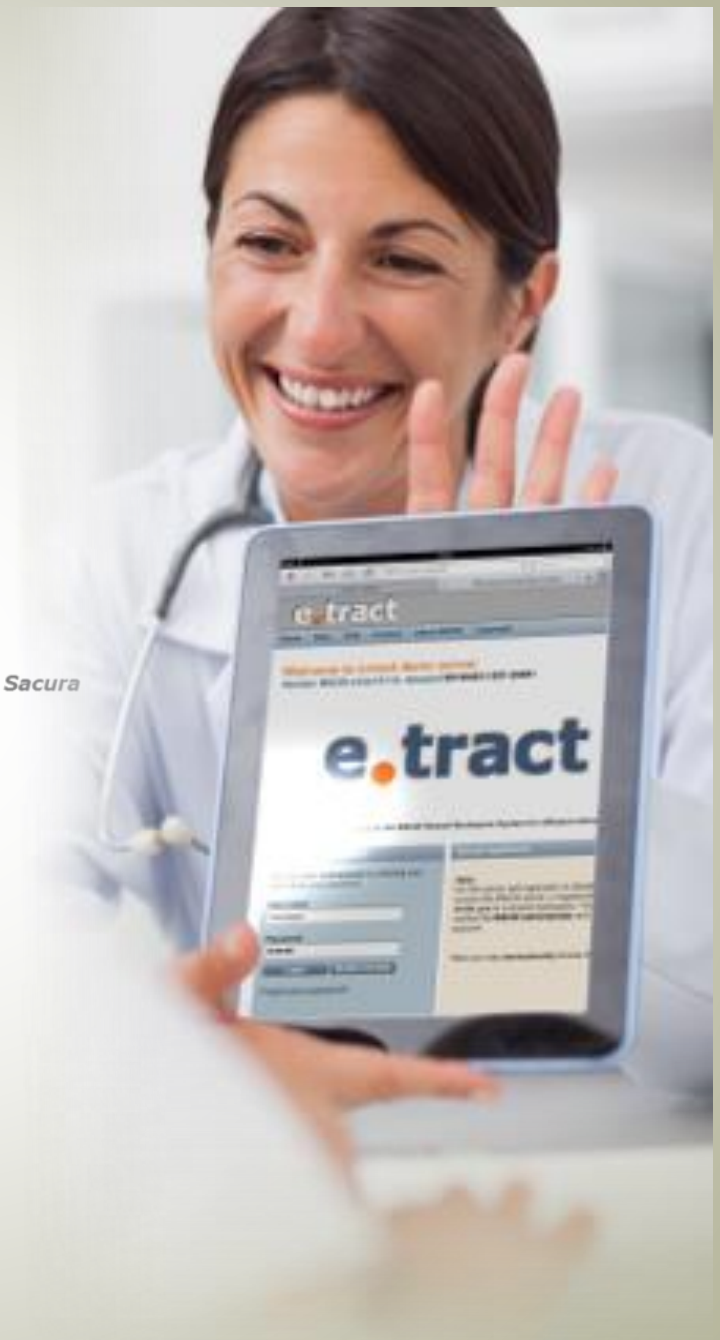
Online Collaboration

OrbiTeam Software and **SACURA** developed **e.tract** based on **BSCW**.

It is an online platform for **secure cooperation of all partners in drug development** including a dedicated clinical trials module by using the current DIA **TMF** Reference Module.

e.tract *a product of OrbiTeam and Sacura*

eCollaboration platform for drug development



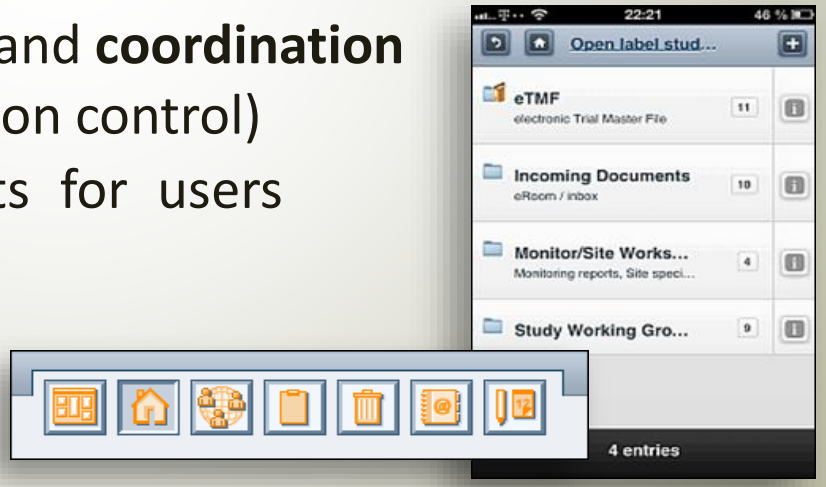
e.tract

e.tract offers the complete functionality of a Collaboration Platform for effective streamlining teamwork:

- Document Management
- Shared Calendars
- Contact Management
- Personal Portal
- Project Management
- Mobile Access
- System Administration
- Workgroups
- Communication
- Task Management
- Polls
- Awareness
- Desktop Integration
- System Integration
- and more …

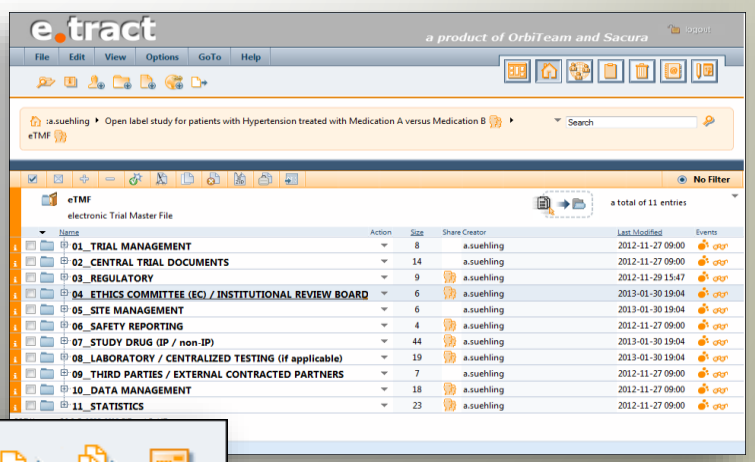
e.tract enables Sponsors, Study teams, CROs and third party providers:

- Storage, managing and archiving of all study related documents
- Real time status
- **Collaboration and communication** in a very comfortable way regardless of time and location
- Managing of **workflows** and **coordination of tasks** (audit trail, version control)
- **Role-based access** rights for users and user groups
- Intuitive use without extensive training



e.tract is characterized by:

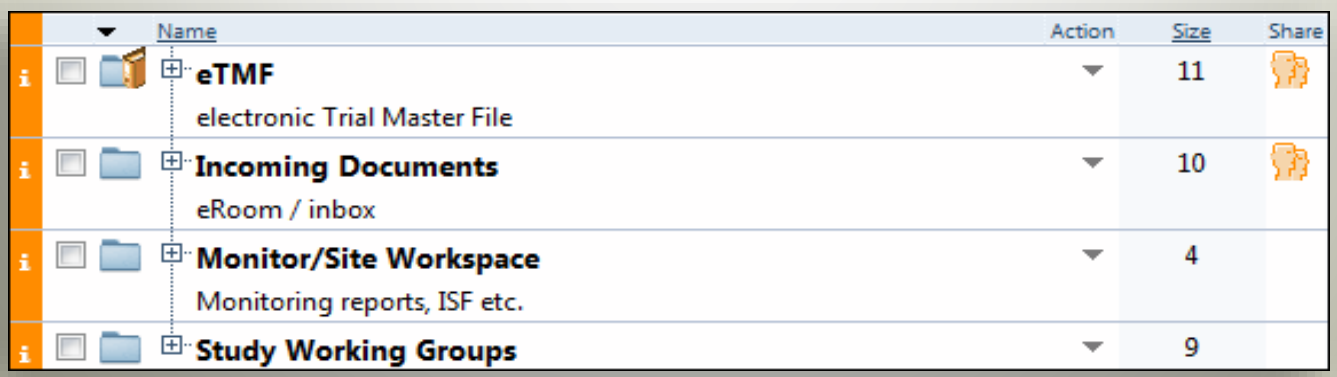
- Use of the current **DIA TMF Reference Model**, version 2.0
- **21 CFR part 11** compliant
- **Easy handling**, no increased training requirements
- Clear roles and responsibilities, improving the cooperation between involved partners
- Increased transparency reduces undue information sharing in the working
- **Standardization** of the collection, storage and management of TMF documents, consistent naming conventions



e.tract

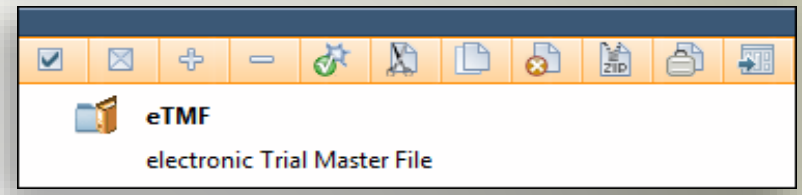
Central domains of this platform are **individually structured workspaces** (**eRooms**),

an electronic **Trial Master File** (**eTMF**) including site management sections.



e.tract

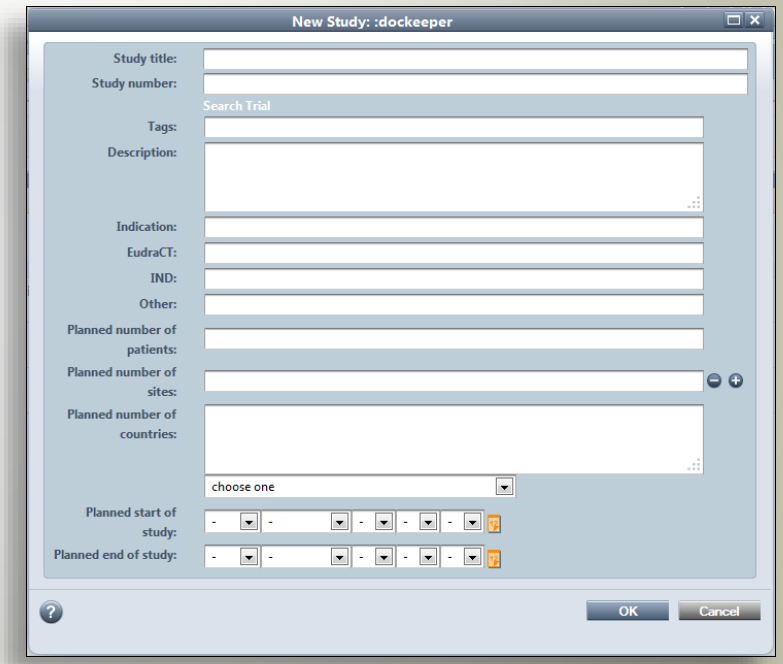
e.tract provides:



- **Guide** through the complex **regulatory requirements** of a TMF
- TMF structure provides clear descriptions and **easy intuitive navigation**
- Simple features to **search for documents** in the eTMF via open text search, tags, descriptions of the documents, indexes, etc.
- **Completeness** and quality of the eTMF
- Continuous **mobile availability** for access to eTMF with smartphones, tablet computers, etc.
- Easy "one click" **archiving of the eTMF**

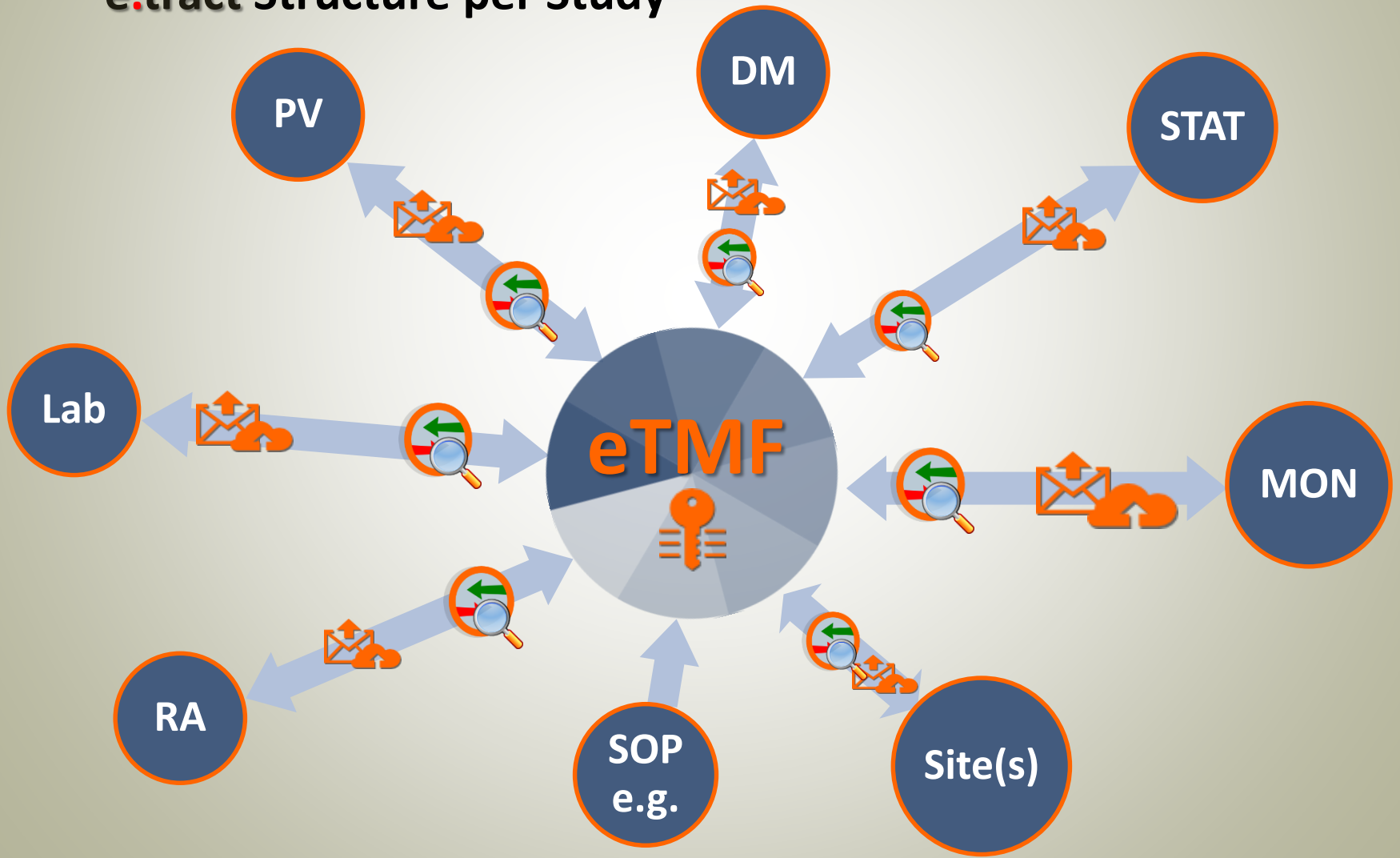
Study Set-up

- Enter the specific **milestones** and conditions of a study. For example:
- **Planned number of patients**
- **Planned number of sites**
- **Planned countries**: choose the countries from the drop down menu.
- **Planned start- and end date of study**
- **…**



A very complex and study-specific collaboration platform with pre-defined working areas, roles, links, archiving structures and workflows is automatically generated.

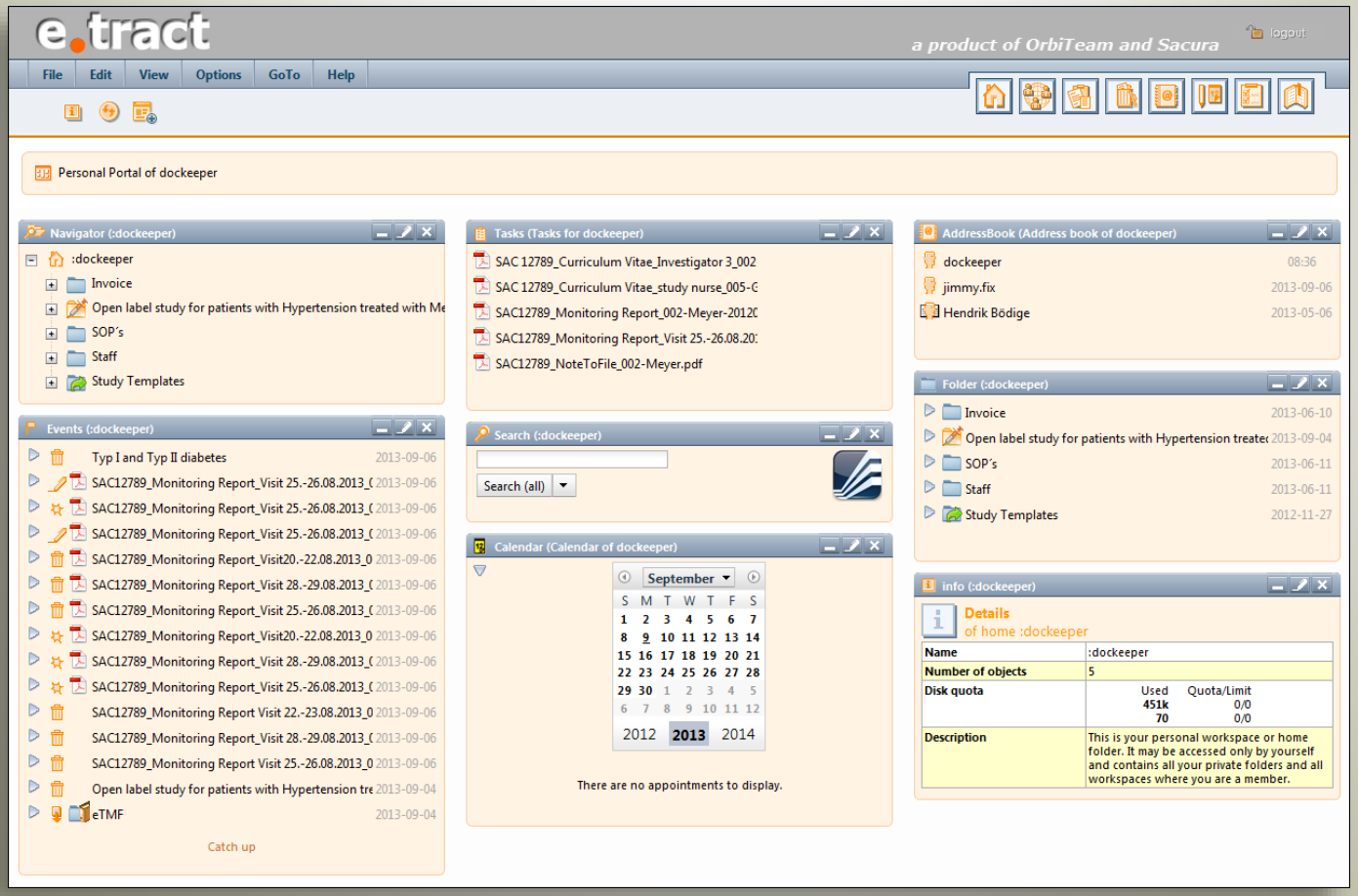
e.tract Structure per Study



The Concept of Roles in e.tract

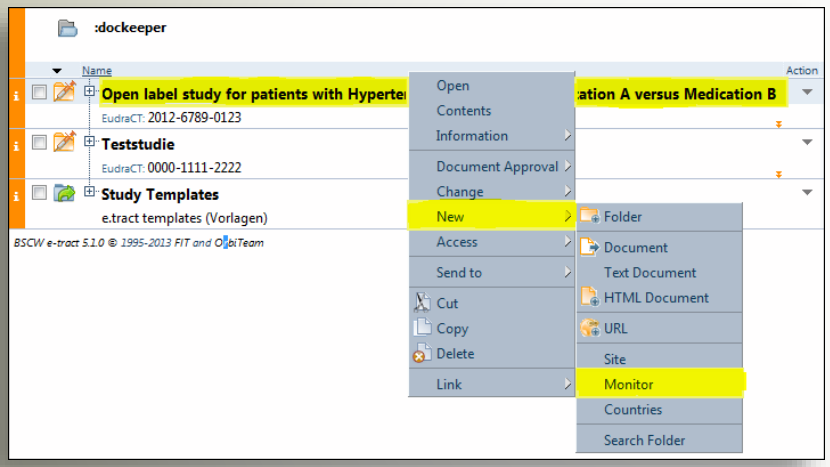
Manager	Associated Member	Restricted Member
Read objects	Read objects	Read only
Copy objects	Copy objects	
Change objects	Change objects	
Cut objects	Cut objects	
Delete objects	Delete objects	
View info pages	View info pages	
Invite members	Invite members	
Cancel invitations		
Change access rights		

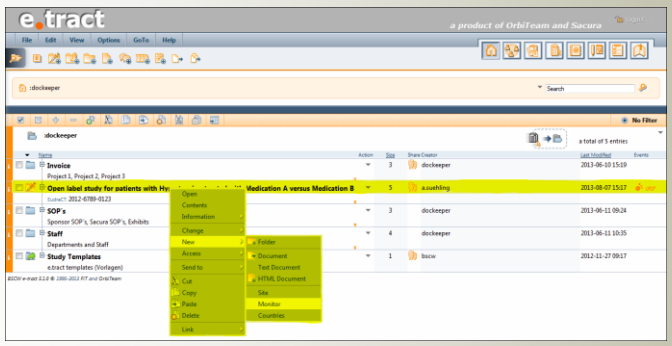
The Personal Portal



Example for role-specific stakeholder

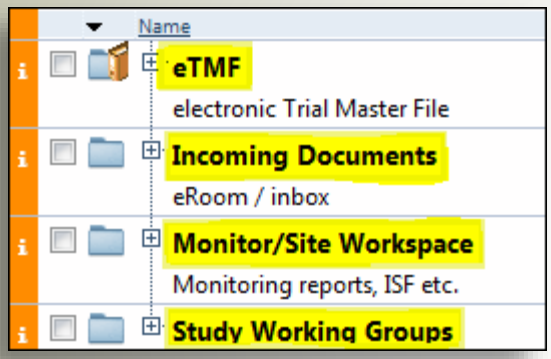
Add a Monitor

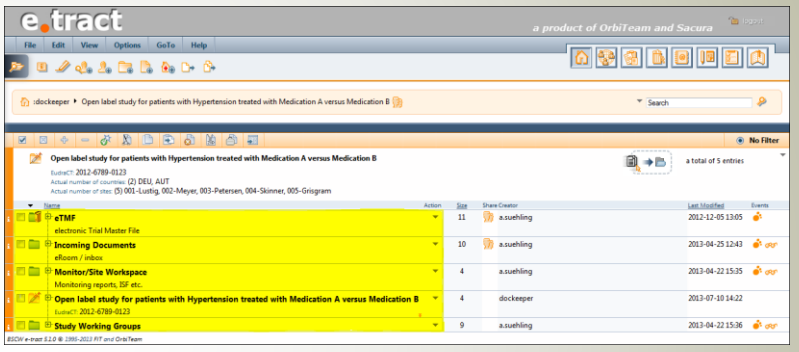




- Within a study, you are free to add a new monitor at any time.
- By adding a new monitor, a workspace and a working group for this monitor is provided initially.
- The monitor has read access to parts of the system and write access to his own **Inbox** and **Workspace**.

Workspaces





- The basic concept of **e.tract** is the system of shared workspace within a study (or a section of the study) for a defined group of users.

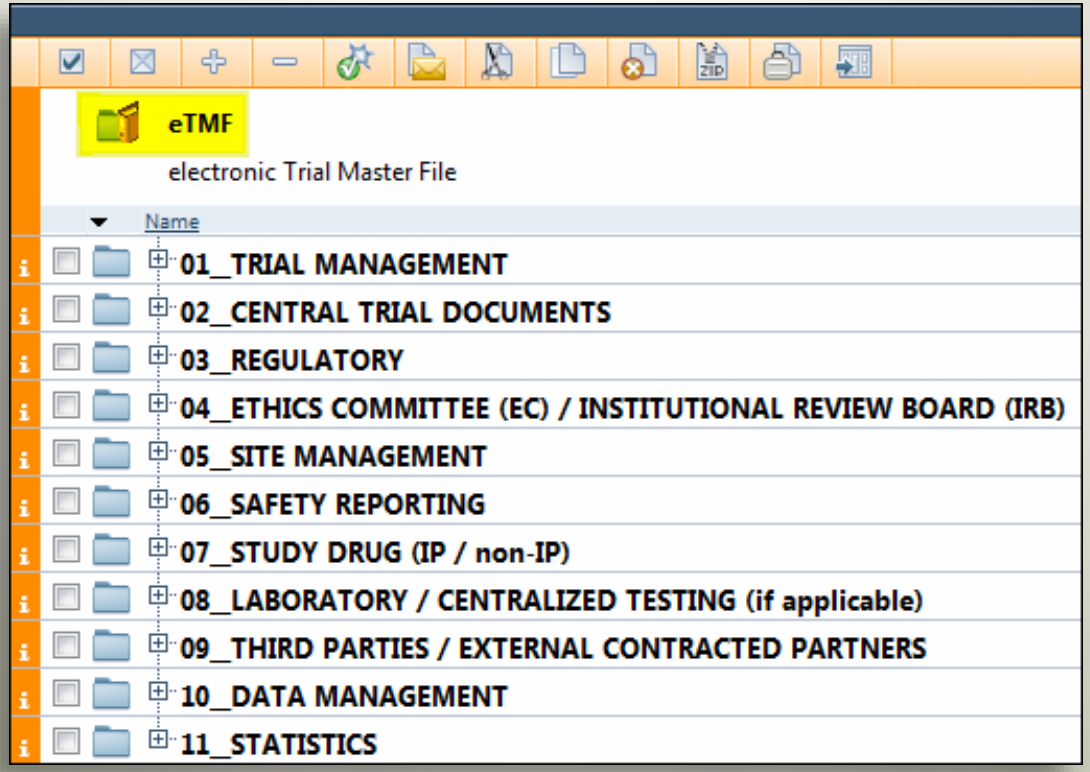
Workspaces

Existing **Working Groups**:

- Data Management
- DocKeeper
- Laboratory
- Manufacturer
- Pharmacovigilance
- Project Management
- Regulatory Affairs
- Statistician

eTMF

The eTMF is divided into 11 areas and about 245 sections:

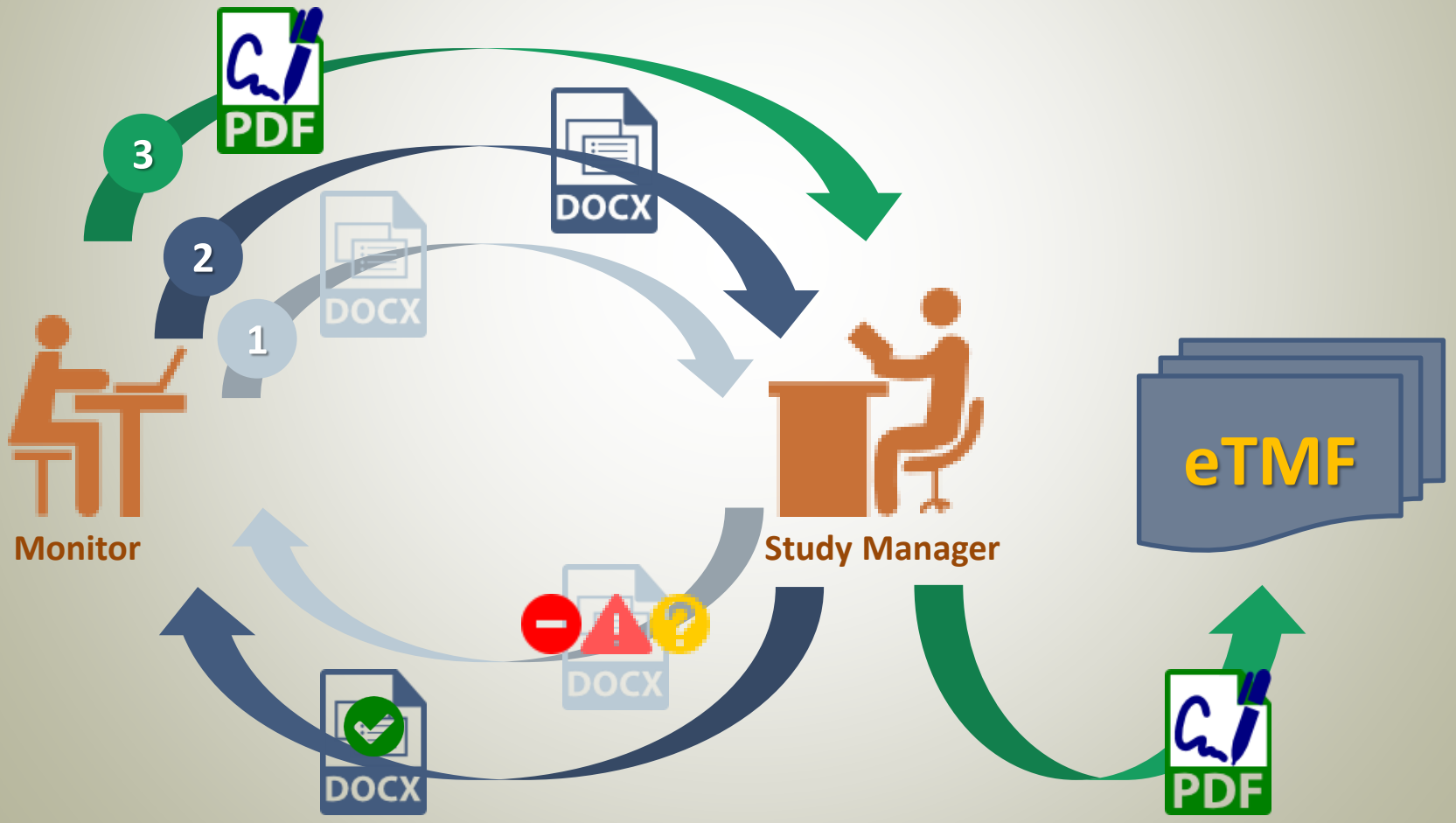


Document Approval, Review and Versioning

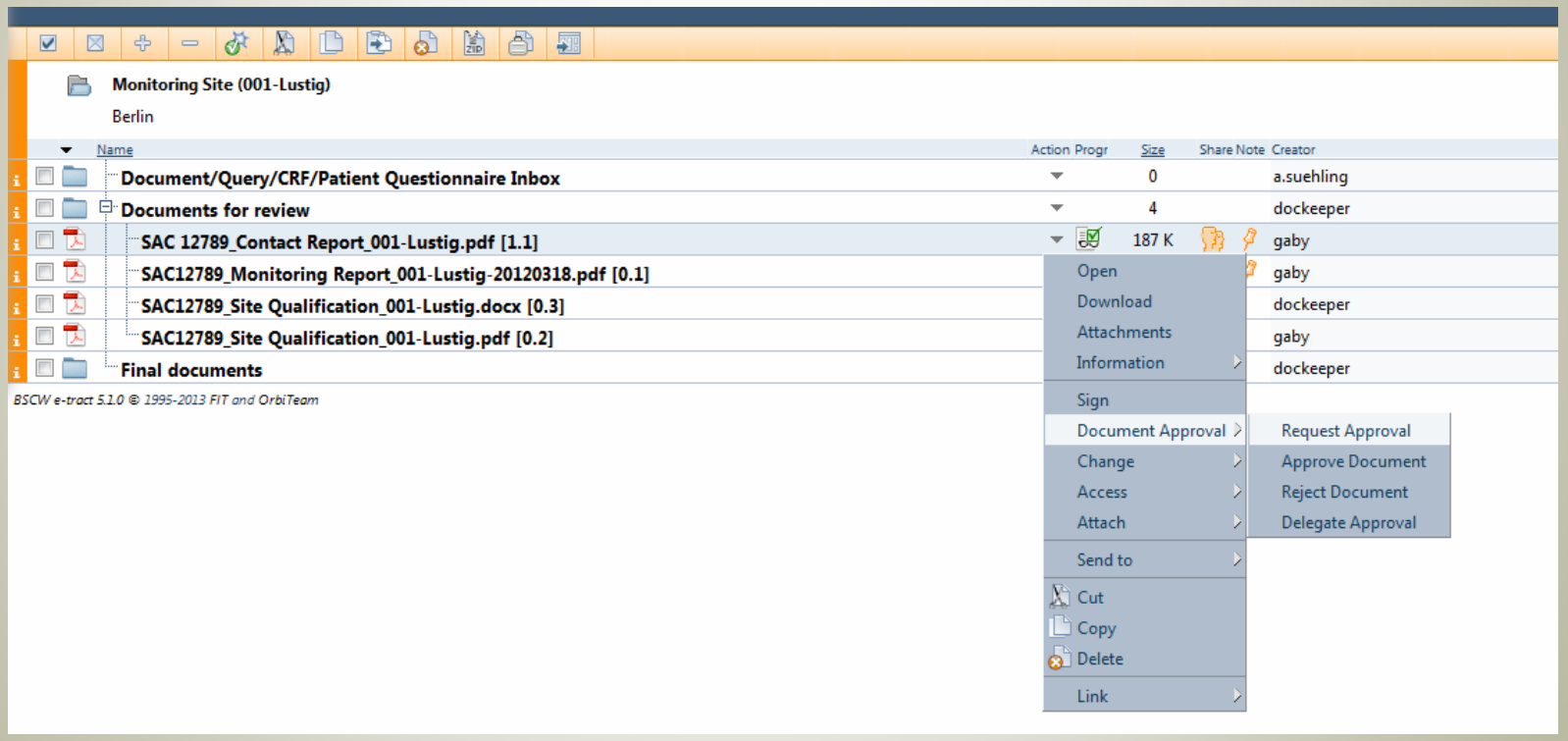
- Consistent and constant comprehensible control- and review processes are indispensable tools in the daily work on clinical trials.

- The **e.tract** system provides an elegant solution that includes review processes, document approval and a constant document versioning, which you can utilize as an audit trail.

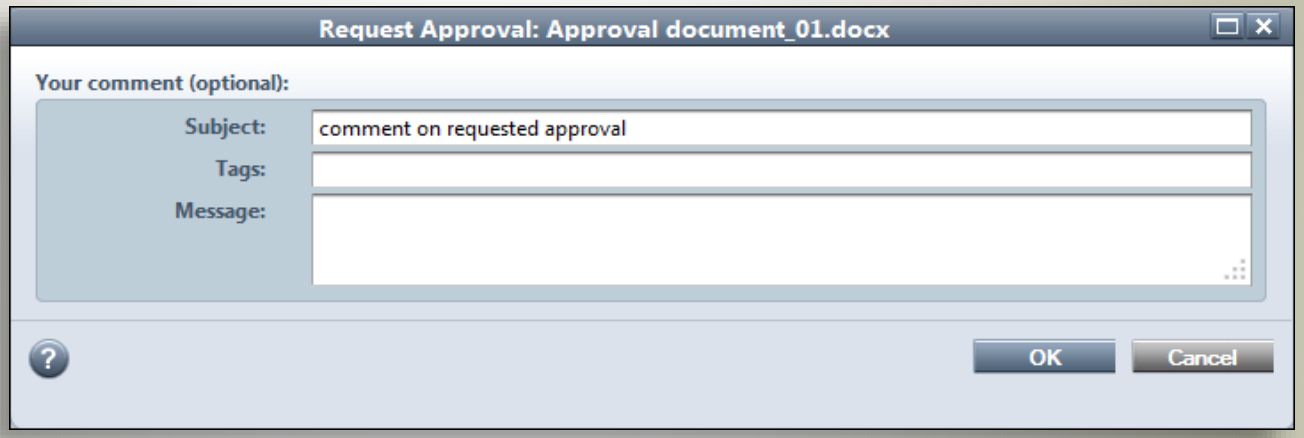
Document Approval, Review and Versioning



Request Approval

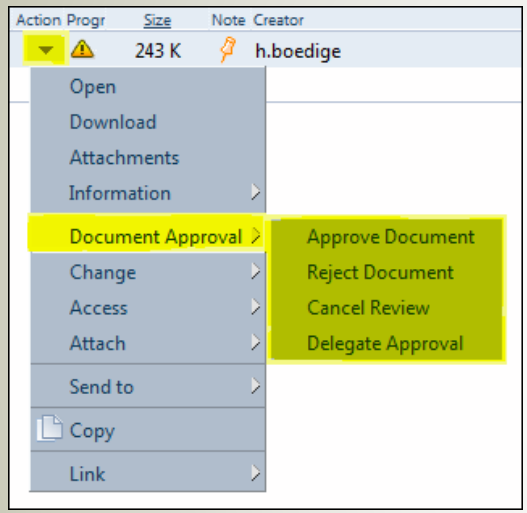


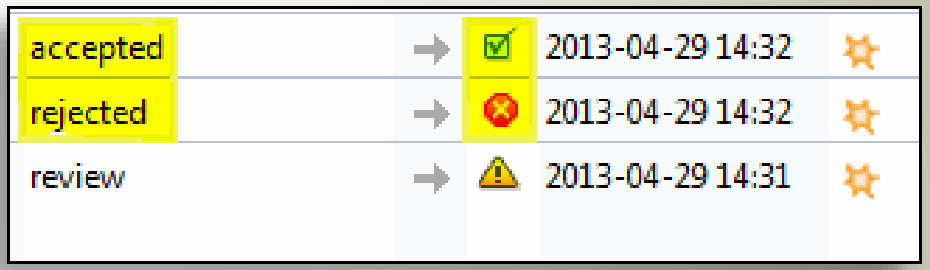
Request Approval



- Add a **memo to the request**
- Responsible reviews the document and rates it by classifying it as **accepted** or **refused**.
- As long as the document is under review it cannot be altered even by the author until a classification has taken place, or the approval has been canceled.

Delegate Approval





- Rating: **Approve Document** or **Reject Document**
- Reviewer also can **Cancel Review** or **Delegate Approval** to another reviewer

Digital Signature

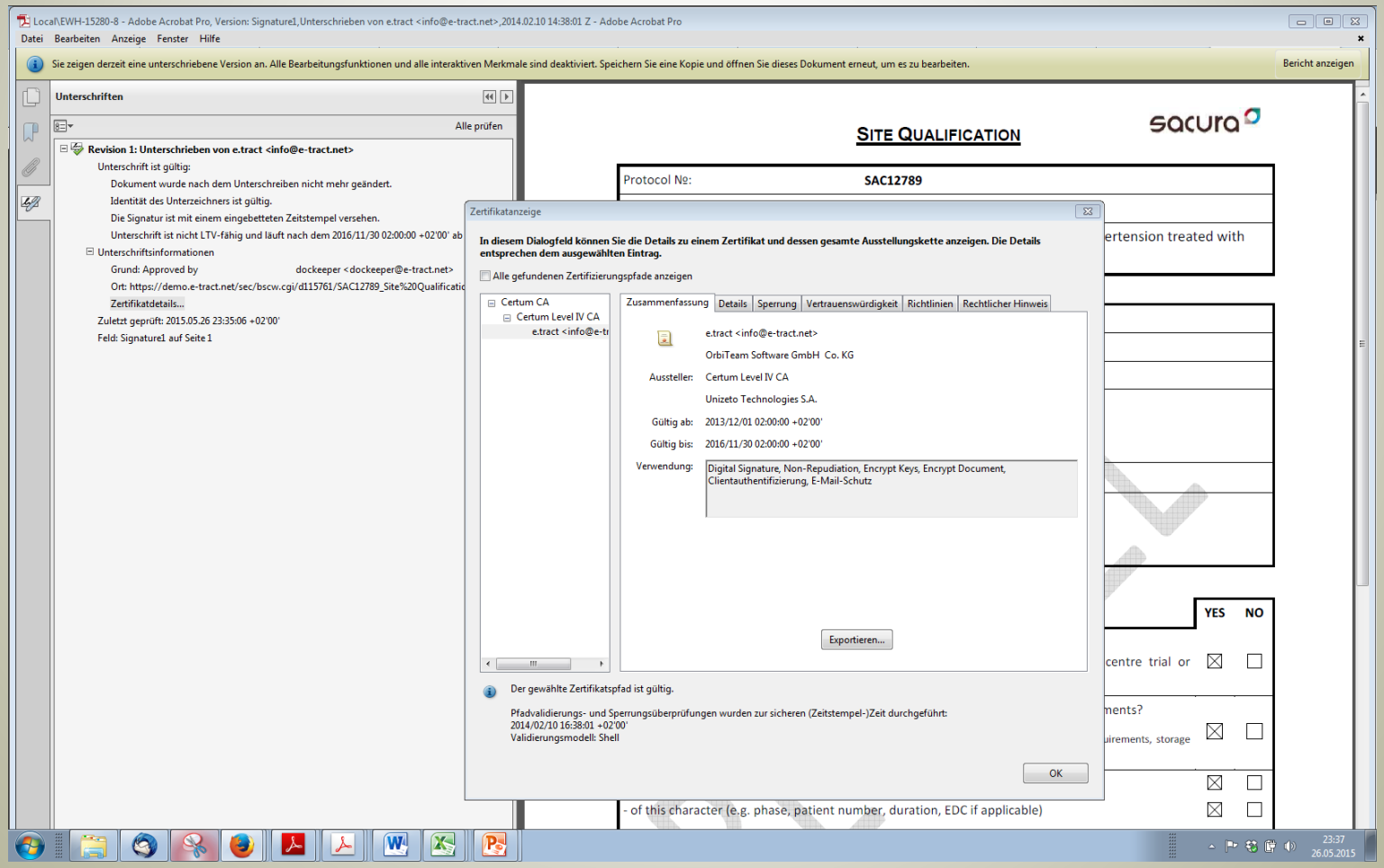
If no, please list main indications of previous clinical trials here:

Indicate the phases of clinical trials the investigator had participated in.	Phase I	☐
	Phase II - III	☒
	Phase IV	☐
Give a number of clinical trials the investigator participated in.		3
Has you / your site ever been audited by EMEA / FDA or Regulatory Authority?		☐ ☒
	If yes, with any major or critical finding?	☐ ☐
Has the investigator any financial or other interests in the investigational product?		☐ ☒
Is a CV attached? You can use Sacura's CV template (Exhibit 25)		☒ ☐

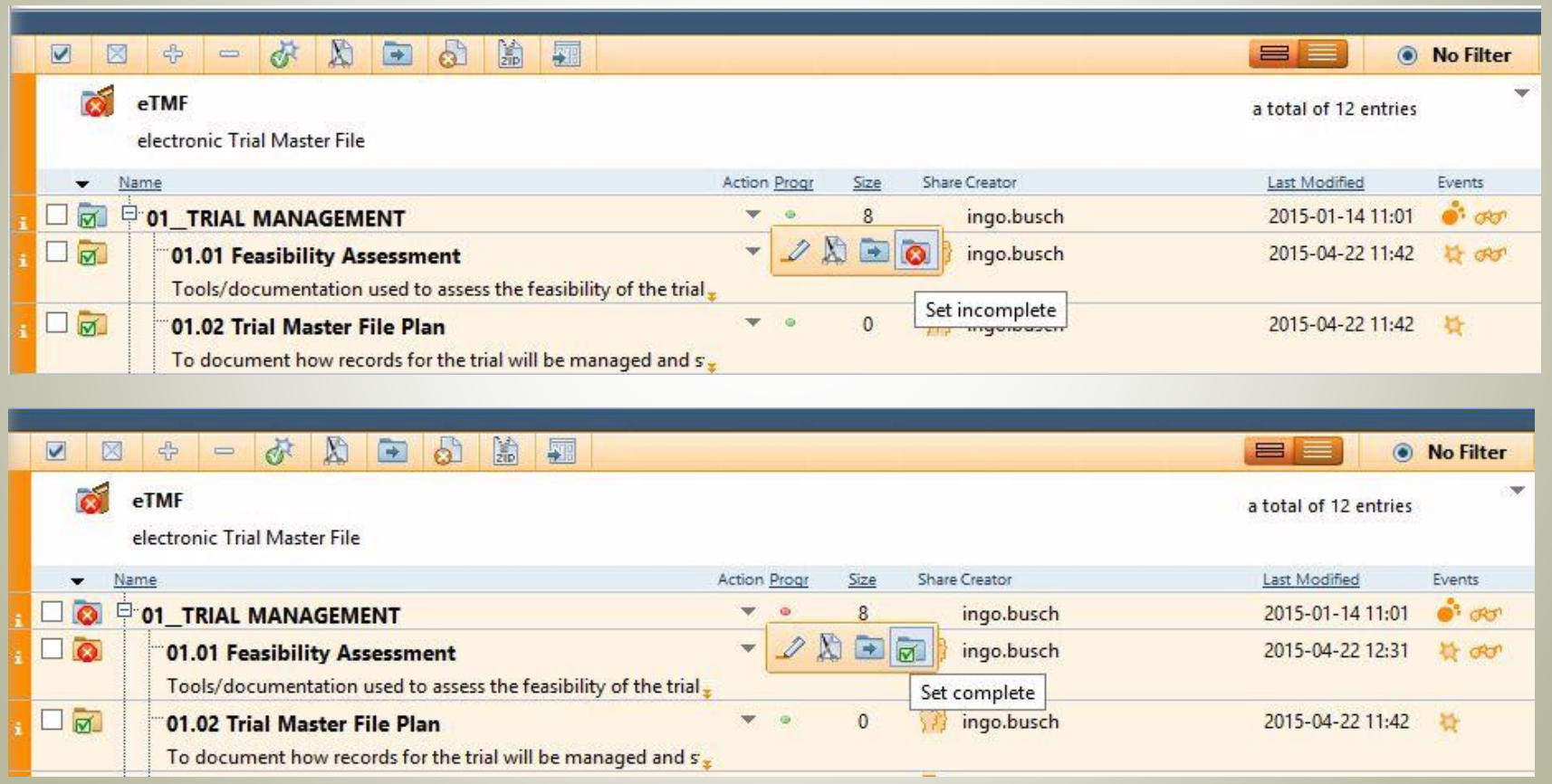
Approved by
dockeeper <dockeeper@e-tract.net>
(via e.tract - https://demo.e-tract.net/)
Date: 2014.02.10 15:37:59 +0100

Approved by
dockeeper <dockeeper@e-tract.net>
(via e.tract - https://demo.e-tract.net/)
Date: 2014.02.10 15:37:59 +0100

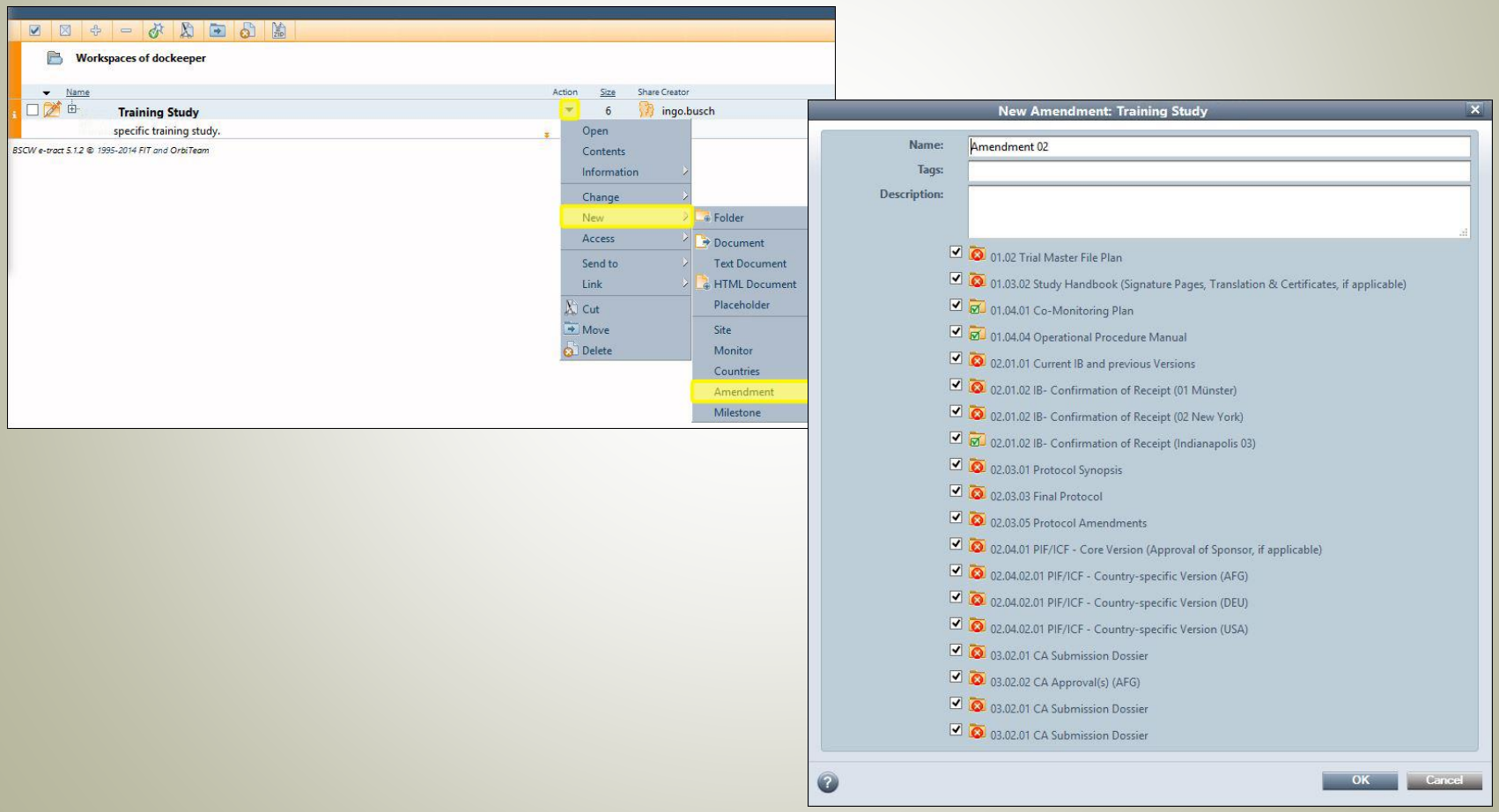
Digital Signature



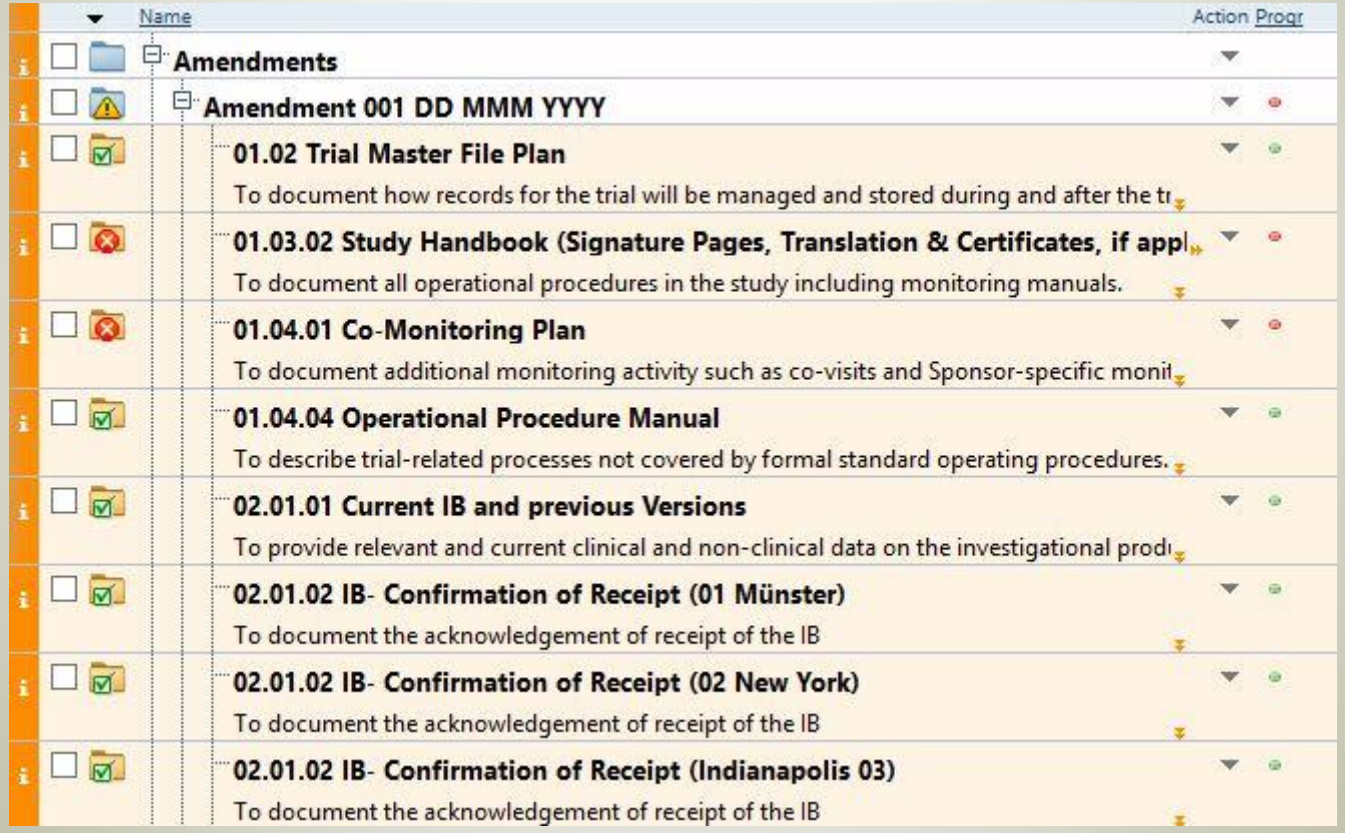
Completeness Monitor



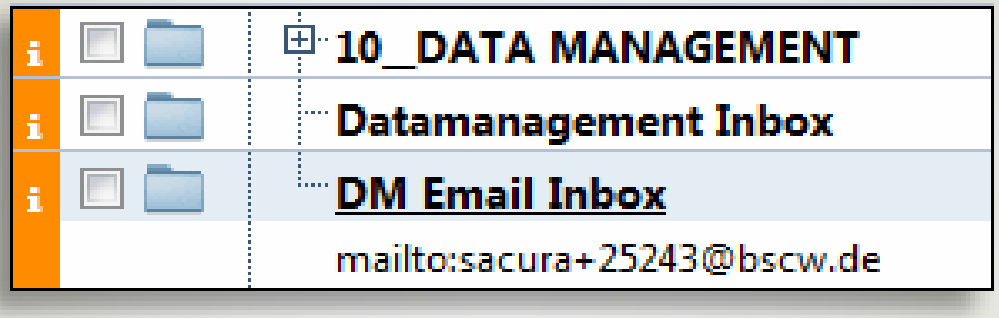
Amendments


Workspaces of dockeeper
Name
Action
Size
Share Creator
Training Study
6
ingo.busch
specific training study.
BSCW e-tract 5.1.2 © 1995-2014 FIT and OrbiTeam
Open
Contents
Information
Change
New
Access
Send to
Link
Cut
Move
Delete
Folder
Document
Text Document
HTML Document
Placeholder
Site
Monitor
Countries
Amendment
Milestone
New Amendment: Training Study
Name:
Amendment 02
Tags:
Description:
01.02 Trial Master File Plan
01.03.02 Study Handbook (Signature Pages, Translation & Certificates, if applicable)
01.04.01 Co-Monitoring Plan
01.04.04 Operational Procedure Manual
02.01.01 Current IB and previous Versions
02.01.02 IB- Confirmation of Receipt (01 Münster)
02.01.02 IB- Confirmation of Receipt (02 New York)
02.01.02 IB- Confirmation of Receipt (Indianapolis 03)
02.03.01 Protocol Synopsis
02.03.03 Final Protocol
02.03.05 Protocol Amendments
02.04.01 PIF/ICF - Core Version (Approval of Sponsor, if applicable)
02.04.02.01 PIF/ICF - Country-specific Version (AFG)
02.04.02.01 PIF/ICF - Country-specific Version (DEU)
02.04.02.01 PIF/ICF - Country-specific Version (USA)
03.02.01 CA Submission Dossier
03.02.02 CA Approval(s) (AFG)
03.02.01 CA Submission Dossier
03.02.01 CA Submission Dossier
OK
Cancel

Amendments


Name
Action
Progr
Amendments
Amendment 001 DD MMM YYYY
01.02 Trial Master File Plan
To document how records for the trial will be managed and stored during and after the tr
01.03.02 Study Handbook (Signature Pages, Translation & Certificates, if appl
To document all operational procedures in the study including monitoring manuals.
01.04.01 Co-Monitoring Plan
To document additional monitoring activity such as co-visits and Sponsor-specific monit
01.04.04 Operational Procedure Manual
To describe trial-related processes not covered by formal standard operating procedures.
02.01.01 Current IB and previous Versions
To provide relevant and current clinical and non-clinical data on the investigational prodi
02.01.02 IB- Confirmation of Receipt (01 Münster)
To document the acknowledgement of receipt of the IB
02.01.02 IB- Confirmation of Receipt (02 New York)
To document the acknowledgement of receipt of the IB
02.01.02 IB- Confirmation of Receipt (Indianapolis 03)
To document the acknowledgement of receipt of the IB

E-Mail Inbox



- An **E-Mail Inbox** is available for each working group, e.g. **Data Management** or **Laboratory**.

- E-Mails can be sent by the members of each working group directly to this folder.

Mobile Access

You are welcome to ask for further information and requests by contacting:

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CEO

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Director Business Development

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