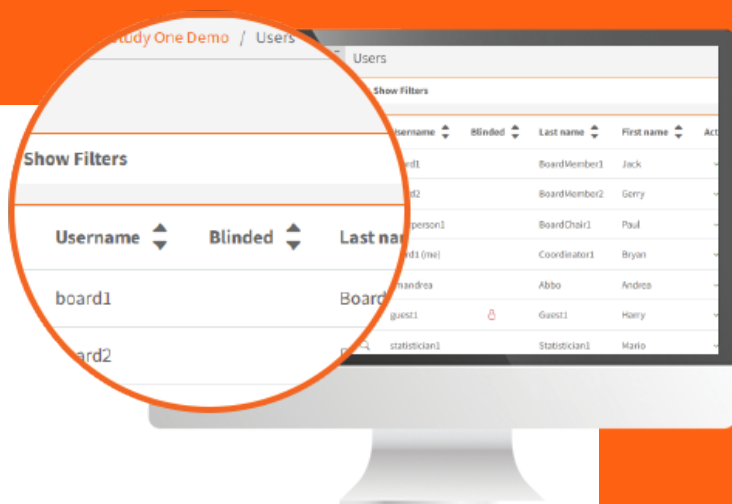




ETHICAL



## eDSMB®

Secure and compliant software solution for DSMBs, DMCs & Steering Committees

### Why use a software for DSMBs, DMCs and Steering Committees?

#### Do you find that:

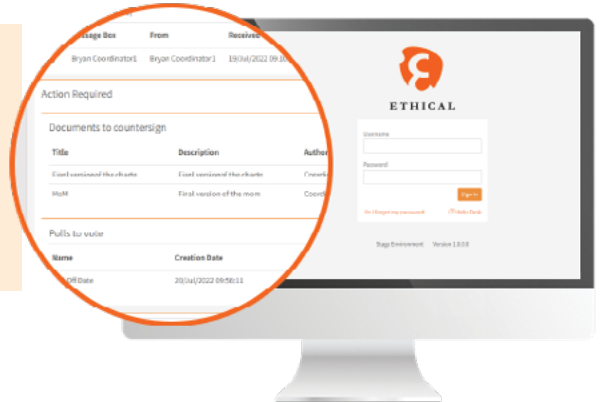
- Documenting the decisions of your committees is challenging?
- Accidental unblinding should be prevented by all means?
- Committee Members' time constraint is an additional difficulty?
- Managing Committee communications and documents is cumbersome?

### eDSMB® is the solution!

- ✓ Audit trail of all your committee activity for GxP compliance.
- ✓ Meeting templates and strict role-based authorizations for data security.
- ✓ User-friendly interface and gentle reminders for preserving experts' time.
- ✓ Assistance to configure, plan and execute meetings for a flawless process.

# eDSMB® Software Features

eDSMB® is a cloud-based software platform that supports all the operations related to your DSMBs, DMCs or Steering Committees



## Meetings

- Integrated calendar
- Meeting templates
- Document viewer
- On-line poll
- Zoom integration (optional)



## Workflow

- Best-practice model
- Reminders for to-do tasks
- Email notifications with direct links
- Secure eSignature
- Role-based dashboards



## Documents

- File manager for documents, emails and notes
- Document templates
- Document versioning
- Flagging of the latest version
- Archive folder for TMF



## Quality & Security

- Blinded/unblinded data segregation
- Strict role-based authorizations
- Two-factor authentication (or SSO integration)
- Audit-trail
- Regulatory compliance

eDSMB® is GxP compliant, secure and validated



- ISO 27001 hosting, backup and business continuity.
- GAMP5 validation documentation and support.
- Secure 21 CFR Part 11-compliant audit trail.
- EU GMP Vol. 4 Annex 11, EU GDPR.



# by Ethical GmbH

## Clinical Committees Trusted Experts

Endpoint adjudication, Protocol Deviations, Data & Safety Monitoring Boards, Data Monitoring Committees and Steering Committees management on cost-effective, compliant software solutions for over 16 years.



**300+** international clinical trials



**10,000+** investigator sites



**100,000+** patients involved



**24+ years** in clinical data management



**16+ years** in clinical committee management



Serving **Sponsors**, **CROs** and **AROs**

Are you interested to know more?

Get a **FREE DEMO** of the  
**eDSMB® Software Solution**

No commitment required from your side.

More info at: [www.edsmb.com](http://www.edsmb.com)