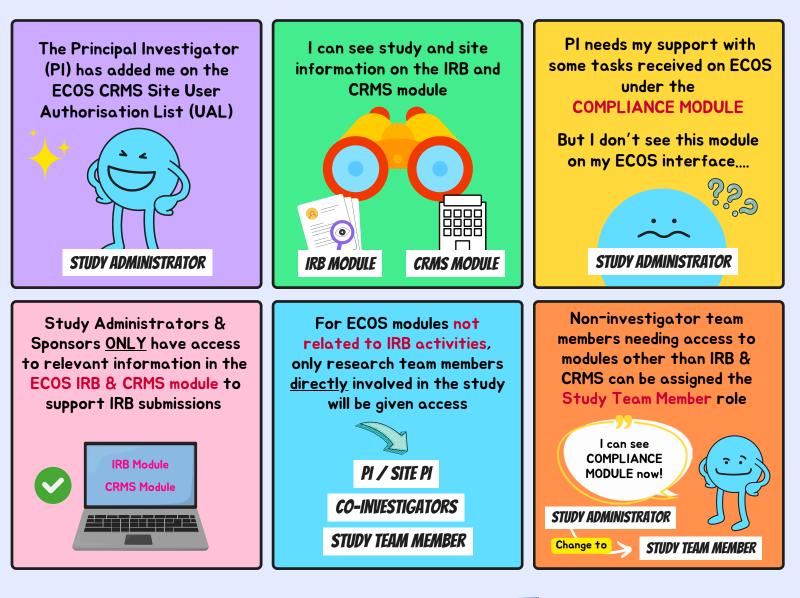


View and Edit Access Rights

ECOS - ATTENTION TEAM MEMBERS!



CRMS ROLES

STUDY TEAM MEMBER

Site personnel **directly involved** in the research conduct e.g. CRCs, Study Nurses, Pharmacists, etc

STUDY ADMINISTRATOR

Site personnel **NOT directly involved** in the research but provides **administrative support** only, e.g. Dept Manager providing research

administrative support

STUDY SPONSOR

Sponsor/CRO personnel, e.g. CRAs

View & Edit Rights

Modules Supporting IRB Submissions

| User Role | IRB Module | CRMS Module | | | | | | | |
|--------------------------------|--------------------|----------------------|--|----------------------------------|-------------------------|---------------------------|--|--|--|
| | Forms ¹ | Study Information | User Authorisation List (UAL) ² | Site Information ² | Milestones ² | Participants ² | | | |
| Study Team Member (STM) | View & Edit | View & Edit | View & Edit | View & Edit | View & Edit | View & Edit | | | |
| Study Administrator (SA) | View & Edit | View & Edit | View & Edit | View & Edit | View & Edit | View & Edit | | | |
| Study Sponsor (SS) | View & Edit | View & Edit | View & Edit | No Access | No Access | No Access | | | |

¹ Initial Application, Amendments, Study Status Report (SSR), Study Deviation/ Non-Compliance Report (DNC), Serious Adverse Event Report (SAE), Unanticipated Problems Involving Risks to Subjects or Others Report Form (UPIRTSO), Other Study Notifications Report Form (OSN).

² Access is site-specific

Modules Supporting non-IRB related Activities

| User Role | Compliance Mod | Compliance Module (PISAF) | Standing Database Module | Monitoring Module | Audit Module | | |
|--------------------------------|--|---------------------------------------|-----------------------------------|----------------------|-----------------|--|--|
| | Study Deviation/ Non- Compliance Report (DNC) | Serious Adverse Event Report (SAE) | Modules To Be Launched On ECOS | | | | |
| Study Team Member (STM) | View & Edit ³ | View & Edit ³ | | WOR | | | |
| Study Administrator (SA) | No Access | No Access | | PROG | | | |
| Study Sponsor (SS) | No Access | No Access | | | | | |

³ Access to edit is granted by RI Secretariat only



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