



## Job Aid for Sites: Florence eISF

This guide aims to assist sites participating in an MSD study to get them up-to-speed on using Florence's eISF.

1

- Site confirms interest in adopting Florence eISF during validation activities

2

- Binder structure will be created by Florence and populated with applicable documents by Sponsor
- Site admin and PI will be provided access by Sponsor (upon training completion)

3

- Fully populated binders released to site no later than SR
- Site admin will provision other applicable site staff with access to binders and maintain site files moving forward
- Monitor will retain access for monitoring activities



## Training and Access

- Florence Training is not study or sponsor-specific and is completed one time only.
- Can't find your certificate? No problem! Contact [support@florencehc.com](mailto:support@florencehc.com) to obtain a copy.
- The link for the training catalog is the same for internal and external users: [MSD Training Catalog](#). Training requirements are role-based. **Review the table below to see what training is right for you!**



*Note: Florence roles are not intended to capture site role (investigator/coordinator/pharmacist/ nurse) but rather the activities each individual will perform within the system. Unblinded users will also need to complete "Basic site user training" to gain access to the eISF.*

| Role Specific Training                     |  |                            |  |
|--|--|----------------------------|--|
| Florence User Role Name                    | Sponsor/Site Role  | Training Name              | User Role Permission   |
| Binder Set-up                              | Sponsor user who will be populating the binders during set-up  | Internal MSD user training | <ul style="list-style-type: none"> <li>- Import/Upload documents</li> <li>- Delete documents, folders</li> <li>- Add and remove users and assign roles to users</li> <li>- Move documents and folders</li> <li>- Rename documents and folders</li> </ul>                                       |
| Site Admin                                 | Site users who can give access to additional users and will be filing documents and making changes in e-ISF (e.g SC or regulatory personnel) | Site Admin Training        | <ul style="list-style-type: none"> <li>- Import/Upload documents</li> <li>- Delete documents</li> <li>- Add and remove users and assign roles to users</li> <li>- Move documents</li> <li>- Rename documents</li> <li>- View all audit trial events for documents, binders, folders</li> </ul> |
| Blinded Monitor                            | CRA (read only access except in Sponsor Inbox)   | Internal MSD user training | <ul style="list-style-type: none"> <li>- View e-ISF and blinded source binder</li> <li>- Upload documents and request signatures in Sponsor Inbox</li> </ul>   |
| Unblinded Monitor                          | uCRA (read only access)  | uCRA Training              | <ul style="list-style-type: none"> <li>- View e-ISF, blinded source, Sponsor Inbox and unblinded source restricted binder</li> </ul>   |
| Study Coordinator<br>Unblinded Study Staff | Site staff (blinded and unblinded) who will use e-ISF to view, upload and sign documents only  | Basic site user training   | <ul style="list-style-type: none"> <li>- Import/Upload documents</li> <li>- Move documents</li> <li>- Rename documents</li> <li>- View all audit trial events for documents, binders, folders</li> </ul>   |
| Study Investigator                         | PI, Sub-I who can view and sign off documents  | Investigator Training      | <ul style="list-style-type: none"> <li>- View documents</li> <li>- Sign documents sent for e-signature</li> </ul>  |
| Blinded QC role                            | CRMs, CRAMs & PLMs conducting oversight activities.  | No training required       | View documents   |



## Next Steps / Adding Additional Users

1. Once Florence confirms the training curriculum has been completed, the site user will receive an email confirming that an account has been created to access Florence.
2. Then, the site's study-specific Florence Binder is created. The site user with the Site Admin role will receive an email from **Florence@researchbinders.com** containing a link to **Join Team**.

When you log into Florence, you will see your eISF includes the following:

- **eISF Folder:** Contains sub-folders to store study specific essential documents.
  - **Blinded or Unblinded Source Folder (OPTIONAL / IF APPLICABLE):** Sites can store blinded or unblinded source as permitted by local regulatory requirements or institution requirements.
  - **Sponsor Inbox:** Binder that allows sponsor users to provide documents directly in Florence after binder release.
3. The Site admin will then be able to add other site users with the appropriate role to the Florence study binder (after confirming appropriate training completion) as below:
    - Log in Florence and select your study and site
    - Under "Settings", select "Team Members"
    - Click on "Add members"
    - In the box, paste the site user email and click "Send"

Once the site user appears in the list, click on the ellipses (...) in the Actions column and add the appropriate role and click "On" to activate the role. Click Save.

- See the various Florence roles and their access in the table above



## Tips for Unblinded Users

Documents containing unblinding or potential unblinding information should be managed in the Unblinded Source Restricted Binder within Florence. The site admin is responsible for giving access to this Restricted Binder, only to unblinded staff and uCRA.

In cases where the Unblinded Source-Restricted binder in Florence is not used (i.e., the site keeps a paper Pharmacy Binder), the unblinded staff and uCRA can still benefit from access to the main binder to view general study documents, such as protocols and manuals. This will avoid printing out duplicate documents in the paper Pharmacy Binder.

| Binder Access                 | Blinded Users | Unblinded Users |
|-------------------------------|---------------|-----------------|
| eISF                          | Yes           | Yes             |
| Blinded Source                | Yes           | Yes             |
| Unblinded Source - Restricted | No            | Yes             |



## Long Term Archiving

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- Florence eISF platform will hold documents for up to 25 years after study closure.
- Documents will be indexed and migrated to Service Provider's environment after the study is closed.
- The binder and its contents will be “locked” for editing and moved to the long-term archive location.
- Site personnel with the “Archivist” role will still be able to access the contents and retrieve documents / download but will not be able to add / removed documents within the archive.
- Auditor role will also be able to see archives and can be given access by the Site Admin if needed.



## eSignatures

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- Can be utilized as per site's Country local regulations.
- Are compliant with MSD requirements.



## Helpful Links & Information

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Florence Landing Page: [Why Florence | MSD](#)

Florence Training Catalog: [MSD Training Catalog](#)

Florence Support: [support@florencehc.com](mailto:support@florencehc.com)

Florence / MSD eISF One-Pager: [What is eISF?](#)

Florence Articles and Demos: [Florence](#)

- **Note: available for registered users- you must sign in to access.**