

DIA Electronic Regulatory Submission Community July 26, 2016 Agenda

- Updates
- 2016 DIA Electronic Regulatory Submissions (ERS) Survey results
- DIA ERS Core Committee members needed:
 - Looking for more active general committee members
 - All specific committee positions have been filled

Updates

- Regulatory Submissions, Information, and Document Management Forum
 - Feb. 6-8, 2017 Bethesda, MD
 - Abstracts due by Monday, August 1, 2016
- DIA Updates
 - Update to eCTD Technical Conformance guide coming soon
 - FDA asking for feedback on 2-way messaging for eCTD 4.0. Should message go back to computer that sent message/submission or always to a particular contact at a company?
- **DIA Annual Meeting Presentations Available Online**
June 26-30, 2016, Philadelphia, PA
 - [Electronic Submissions Update, Ginny Hussong, Director, Division of Data Management Services and Solutions, Office of Business Informatics, CDER](#)
 - [Electronic Submissions Gateway \(ESG\), La Misha Fields, Program Manager, OIMT](#)
 - [Electronic Submissions Gateway: Next Generation eCTD v4.0 Two-Way Communication, Mark Gray, Senior Project Manager, CBER](#)

FDA ESG Updates

- The FDA Electronic Submissions Gateway (ESG) has announced the following changes:

1. Letters of Non Repudiation May be Submitted Electronically:

- Users requesting a new ESG account must send an electronic copy of their Letter of Non Repudiation to ESGHelpDesk@fda.hhs.gov. In addition, users must send a physical copy to the FDA. Users must send a hard copy within 2 weeks or your account may be disabled. For more information on Letters of Non Repudiation and the FDA mailing address, please click [here](#).
- **Benefit: sending an electronic copy of the Letter of Non Repudiation will make the registration process significantly quicker.**

2. Single account for CROs or Consultants (or U.S. Agents):

- CROs or Consultants are no longer required to register for separate accounts for each of your clients. You are now only required to have one ESG account for submissions for all clients. For Steps for CROs, U.S. Agents and Consultants to obtain ESG accounts, please click [here](#).
- **Benefit: maintaining a single account for all clients will make account management easy for CROs and Consultants.**

Additional Discussion

- Ask that links open to new window instead of open to user preference.
 - Pdf specifications
 - Table of Contents for more than 4 pages