CLINICAL TRIALS TRANSFORMATION INITIATIVE

CTTI Recommendations: Desired Attributes of Electronic Portals for Expedited Safety Reporting

An ideal system for sharing expedited IND safety information with investigative sites is through a central portal used by all sponsors in order to improve efficiency and reduce paperwork burden (recognizing that electronic systems may not be feasible for all study sponsors). However, until use of a single, central portal is feasible, electronic reporting portals should have consistent functionality and include the following attributes:

Overall System Functionality

1. Browser independent (i.e., should work seamlessly with all commonly used browsers)
2. Operating system independent
3. Mobile-friendly
4. Quick report download time (i.e., externally hosted, cloud based)
5. Simplified system for managing security (e.g., end-user control over password management, biometric identification in lieu of passwords, and/or ability to integrate with various identity access applications)

User Interface

6. Intuitive, easy-to-navigate interface (e.g., few "clicks" required to access safety reports directly; safety report can be accessed directly via hyperlink contained in an email notification)
7. Flexibility within the portal for use with varied institutional processes

Report Management & Analysis

8. Ability to print reports or download multiple reports with one click to a compact disc, computer or electronic investigator site file
9. Ability to filter reports by event so follow up safety reports do not appear as "new" events
10. Ability to search and display safety reports using custom dates, by country of origin and/or event name
11. Allows for export of single reports as well as aggregated data
12. Ability to drill down to single reports/write-ups
13. Reports remain visible for the life of the trial

Report Notification, Acknowledgement and Verification

14. Ability to batch safety report notifications (per day/week) as per investigative site user's preference
15. Ability for PI to delegate the task of accessing safety reports via portal to another person at the site
16. Easy acknowledgement of safety reports by investigative site staff (e.g., click on a link to the report, check a box or check-all option)

17. Ability to send and record acknowledgement of a safety report only once across multiple trials for the same investigational product, yet still showing the report under each trial
18. End to end audit trail that can be printed and saved/stored for future reference by both the sponsor and investigative site, possibly including, but not limited to:
    - Report date
    - Report number
    - Compound
    - Trial #
    - Date report made available via portal
    - Date report accessed by the site
    - Name of the user that accessed the report
    - Whether report was saved/downloaded/printed by site user
19. Ability of the sponsor to document delivery of reports within the portal if an alternative means of reporting is required (i.e., the sponsor cannot access the portal and requires hard copy)
20. Allows for two-way communication about safety reports between the investigative site and sponsor

Investigator Sign-off

Consistent with US FDA guidance, an electronic sign off requirement by the Principal Investigator or other investigative site staff is not a desired attribute.

Investigative Site Education

Improved education for investigative sites, including guidance not only on portal functionality, but also regarding best practices for incorporating portal management into site report management processes, is important to support appropriate use of the portal. For example:

- How does use of a new portal change overall work flow of the study team, and if so, how will that be managed?
- Will the IRB requirements for hard copy reports and/or investigator sign off change?
- Providing reminder to designate source of email sender as not spam.

Finally, we recommend usability testing for portal-related educational material.

- *These recommendations are based on results from the IND Safety Advancement Project.*
- *CTTI's Executive Committee approved the recommendations.*
- *Released in December 2015*