DIA Electronic Regulatory Submissions (ERS) Community Monthly Agenda & Meeting Minutes	
Date and Time	Tuesday, April 26, 2016 – 11:00 AM Eastern Standard Time (EST)
Agenda & Meeting Minutes	*General Business:* 1. 2016 DIA Electronic Regulatory Submissions (ERS) Survey a. The DIA ERS Community Core Committee wants to improve the experience for the ERS Community Members. To accomplish this, we are conducting a yearly survey to make sure relevant topics are being discussed. Obtaining the Community members feedback is vital to this process, please let your voice be heard. We would greatly appreciate you taking about 10 minutes to complete the survey. Your responses will be kept confidential and will not be identified by individual or company. All responses will be compiled together and analyzed as a group. You will receive a copy of the survey results. Take the survey here: https://www.surveymonkey.com/r/diaers2016 2. DIA 2016 Annual Meeting: Engage and Exchange Session a. Adair Turner & the ERS Community are hosting a Round Table: Tuesday, 4:00pm – 5:00pm; Topic will be Regulatory Operations Systems and Processes 3. DIA ERS Core Committee members needed: a. Looking for more general committee members b. Need to also fill specific positions: i. <u>Education Coordinator</u> • Lead the development of a schedule for Community Webinars, Teleconferences, and Education related Documents and Guides. • Coordinate with Speakers and Presenters to schedule webinars and teleconferences and ensure that presentation materials are available before the scheduled event. • Announce educational events using the Communities Platform and create "Events" for downloading. ii. <u>Member Engagement Coordinator</u> • Working with the Core Committee and DIA staff, coordinate the development of opportunities for members to share their expertise through large, small and micro-projects. • Identify working group needs and coordinate with Working Group leaders to develop projects, guidance and best-practice documents, and otherwise encourage member engagement. • Work closely with the Communications Coordinator to gauge Community member participation and solicit feedback on Community activities.

	iii. Programing Coordinator
	• Encourage and facilitate member participation in abstract submission for DIA meetings.
	• Keep the Core Committee and Community Members updated on upcoming DIA events that are relevant to Community members.
	• Coordinate with the Program Committee members of specific meetings to communicate Community needs and suggestions for upcoming meeting programing.
	iv. Communications Coordinator – Position Filled
	• Develop and maintain a system for informing Community members of activities and relevant information.
	• Act as administrator for DIA Community website: keep the site clean, keep content up to date, keep access accurate.
	• Use communications to help coordinate and ensure delivery of action items and associated deliverables.
	• Help committee chairs with communication and site activity (eg, posting agendas and minutes), as needed.
	Webinar by Olga Alfieri: Highlights of US FDA Regulatory Compliance Roadmap and SEND Standardized Study Data Requirements*
	• Highlights of FDA Submissions Compliance Roadmap
	• What is SEND?
	• SEND Implementation Timing
	• SEND Strategies Timetable
	• Studies in Scope for SEND under SENDIG V3.0
	• How to Prepare for SEND READINESS –Experience
	*Slides available on DIA ERS Community Page
Action Items	• Complete the 2016 DIA Electronic Regulatory Submissions (ERS) Survey by Thursday June 30th.
	• Invite others from outside the DIA ERS community to take the survey.
	• Join the Core Committee and help shape the DIA ERS Community.