DIA Policy 43 Subgroup MEETING MINUTES

22 January 2021
10:00 AM Eastern Time

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1	**Approx. 16 participants on the call.**	
2	The call included questions/answers from meeting participants. A few participants on the call have had experience with Health Canada's (HC) Public Release of Clinical Information (PRCI), which involves both retrospective and proactive requests for redacted submission documents. They shared some of their experiences and opinions with HC thus far, which is captured in these notes. Readers should still follow HC's PRCI guidelines regardless of comments contained herein.	
3	Joyce Hauze (Mallinckrodt) asked if CSRs are written with Disclosure and anonymization in mind? Numerous people said sponsors are implementing changes with how CSRs are written due to future disclosure. Some put the list of vendors in the appendix instead of in the CSR. Quality by Design was quoted as a process to follow. Sponsors that leave mini-narratives in text find it problematic for redactions.	
4	Laura Dodd (Takeda/PRA) asked when HC PRCI will start stage 2. Kavitha Verma (MMS Holdings) informed us the HC timeline was shared at the last DIA conference; "Year 2" will start 20 March 2021. As noted in the January meeting minutes, Health Canada's stage 2 will be in scope as of 20 Mar 2021. That includes: • ALL new drug submissions (NDS); • Supplemental new drug submissions containing confirmatory trials (SNDS-c) following the issuance of a notice of compliance with conditions as agreed to in the Letter of Undertaking; • Submissions to switch an authorized medicinal ingredient to non-prescription status (Rx-switch for full switch and partial switch submissions), AND • COVID-related new drug submissions	
5	Bob Paarlberg reported that HC's guidance is being updated with the help of EMA.	
6	Wendy Wimmer (Merck) asked if anyone else took out signatures and put an overlay of the typed name over it if the typed name did not appear immediately below the signature, as noted during the PHUSE mtg? Attendees agreed they remove the signature but do not include an overlay of the typed name for HC; including for a package that was just published at end of year.	
7	There was a question if HC is using the Gateway (ie, their typical regulatory exchange for passing documents).	

	Wendy said if the original submission went through the Gateway, then HC wants the redacted document to also be sent via the Gateway. However for older packages (retroactive requests), they'll ask you to send via a secure drop box.	
8	Has anyone received >1 retroactive request at a time? Anna Lee (Lilly) responded they had received 2 at once last year; HC told them to do one, then start on the next one. Wendy clarified that in her experience, once 1 is published by HC, HC sends a notice of the timelines for the next one.	
9	Has anyone received any Freedom of Information Act (FOIA) requests from HC? If so, what was the timeline? Laura said she has processed a number of these; they are due back in 20 days. If the volume of pages is large, ask for more time right away. Also, when HC send completed (fully redacted) documents back, check that all agreed-to redactions were made and number of pages are the same. In a recent package, HC added ~20 pages that were sprinkled throughout a large package and numerous agreed-to redactions were not implemented.	
10	Main landing page for Clinical Information on Drugs: https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/clinical-information-drugs-health-products.html Policy: https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/profile-public-release-clinical-information-guidance/document.html Background/consultation on the policy: https://www.canada.ca/en/health-canada/programs/consultation-public-release-clinical-information-drug-submissions-medical-device-applications.html Redacted submission packages posted on HC site: https://clinical-information.canada.ca/search/ci-rc	
11	The working group agreed to meet in 2 months at this time. **Next Call scheduled for Thursday March 18 at 10am EST.**	---