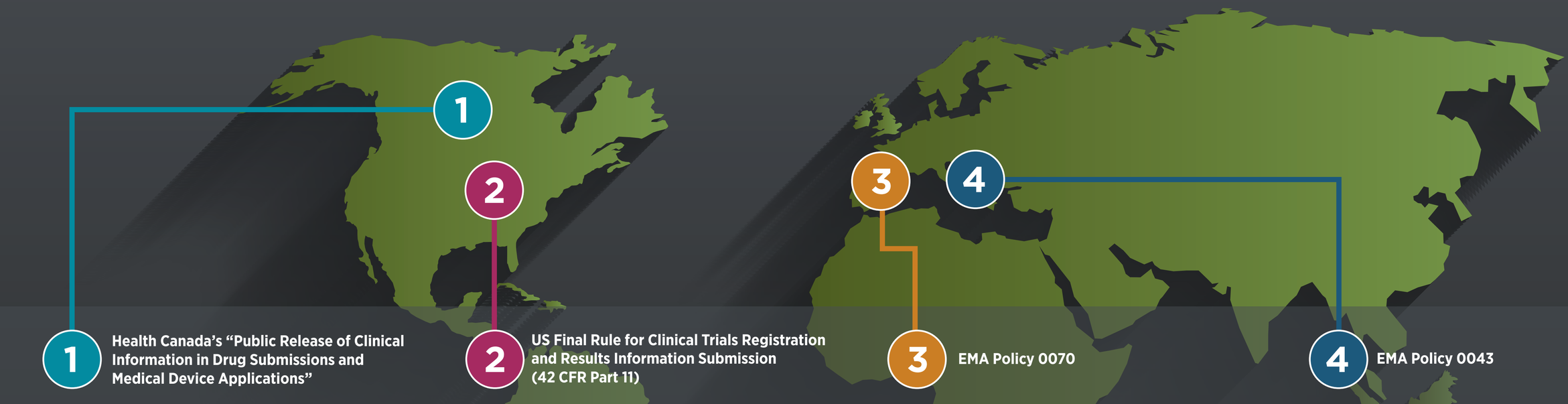
4 RELEVANT REGIONAL CLINICAL TRIAL REGISTRATION AND TRANSPARENCY GUIDELINES CLINICAL DISCLOSURE PROFESSIONALS NEED TO BE FAMILIAR WITH:



1 Health Canada's "Public Release of Clinical Information in Drug Submissions and Medical Device Applications"

- On March 10, 2017, Health Canada published a White Paper to introduce regulations and supporting guidance to permit public release of clinical data in drug submissions and device applications post final regulatory decision
- Health Canada requested stakeholder feedback with the intent of gathering early input to inform implementation of the regulatory proposal and subsequent stakeholder engagement activities

? Key Questions related to this Rule to be addressed at #CTD19:

- How are regulators thinking about public access to regulatory documents?
- What are the other legislative changes at Health Canada that facilitated the development of the proposal?
- What are the similarities and differences in the implementation in EU, US, and Canada?

! Looking for additional opportunities to connect with Health Canada? Check The DIA Annual Canadian Meeting, November 5-6.

2 US Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)

- Effective January 18, 2017, the Final Rule describes the requirements for submitting clinical trial registration and summary results information to ClinicalTrials.gov
- Elaborates on the 2007 FDA Amendments Act (FDAAA) and includes additional data disclosure requirements for trial registration and result reporting

? Key Questions related to this Rule to be addressed at #CTD19:

- What are the requirements to report results under the Final Rule?
- How does the Final Rule impact current processes within companies and research institutions?
- How is NLM is interpreting the Final Rule requirements?

Reference:

https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission

3 EMA Policy 0070

The purpose of the Policy is to help:

- Encourage innovation and development of new medicines while avoiding duplication of clinical trials
- Promote public trust and confidence in EMA's scientific and decision-making processes
- Provide researchers the opportunity to re-assess clinical data

? Key Questions related to this Policy to be addressed at #CTD19:

- How are regulators thinking about public access to regulatory documents?
- What are best practices for anonymization of clinical reports?
- What are the similarities and differences in the implementation in EU, US, and Canada?

References:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/02/news_detail_002697.jsp&mid=WC0b01ac058004d5c1

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/02/WC500221814.pdf

4 EMA Policy 0043

In February 2017, EMA launched a public consultation on the revision to Policy 0043, originally published in 2010. Policy 0043 describes the EMA rules on access to documents.

The purpose for revision is to:

- Expand the scope of the policy to include explicitly corporate documents
- Take into consideration the Agency's proactive approach to transparency

? Key Questions related to this Policy to be addressed at #CTD19:

- What are the new features of EMA Policy 0043?
- How will the revised policy impact companies?
- What are some strategies companies can begin implementing now to prepare for the Agency's proactive approach to transparency?

! Join DIA's CTD Community to get answers to these questions and others!

Not a DIA Member? Sign up now!

References:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/02/news_detail_002697.jsp&mid=WC0b01ac058004d5c1

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/02/WC500221814.pdf

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Get a comprehensive view of current clinical data disclosure regulations, and methods for successfully and effectively implementing the new policies at DIA's Clinical Trial Disclosure and Data Transparency Conference

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