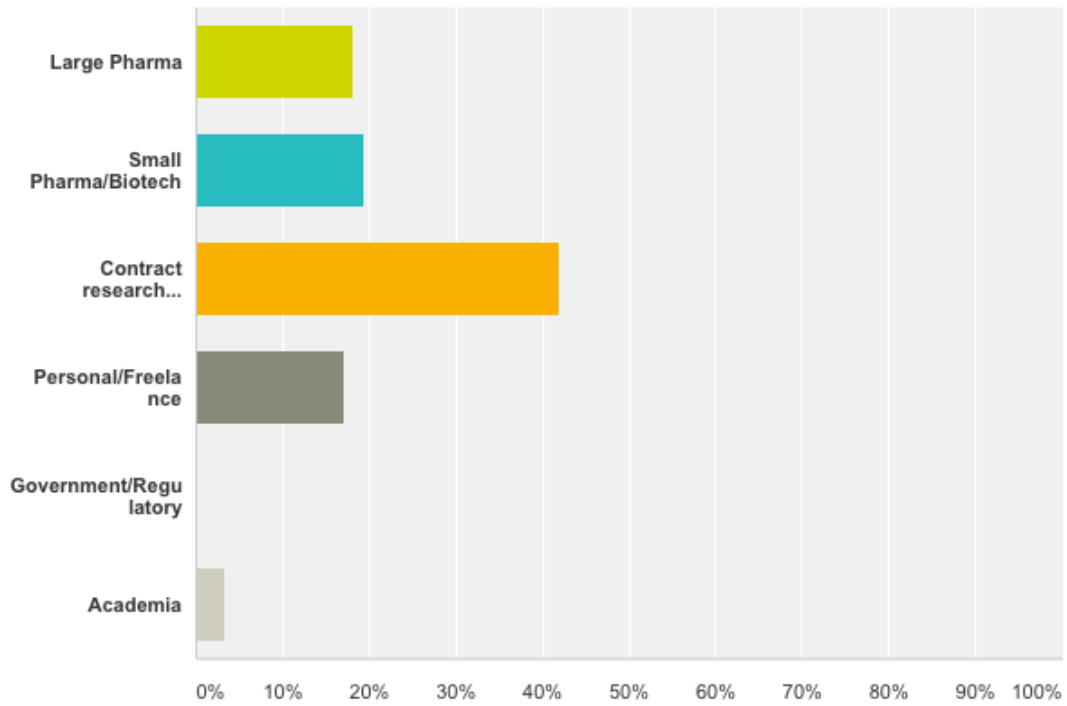# CORE Reference May 2017 Update

EMWA Symposium Conference Report Including CORE Reference Utility Survey Results

At the 5th EMWA Symposium "Transparency and Disclosure of Clinical Regulatory Documentation" in Birmingham, UK on 04 May 2017, Tracy Farrow shared data gathered via the CORE Reference Utility Survey (22 March – 21 April 2017) on how CORE Reference is used in practice. A total of 88 individuals responded. Results, based mostly on multiple response questions (hence percentages do not always sum to 100%), were as follows:
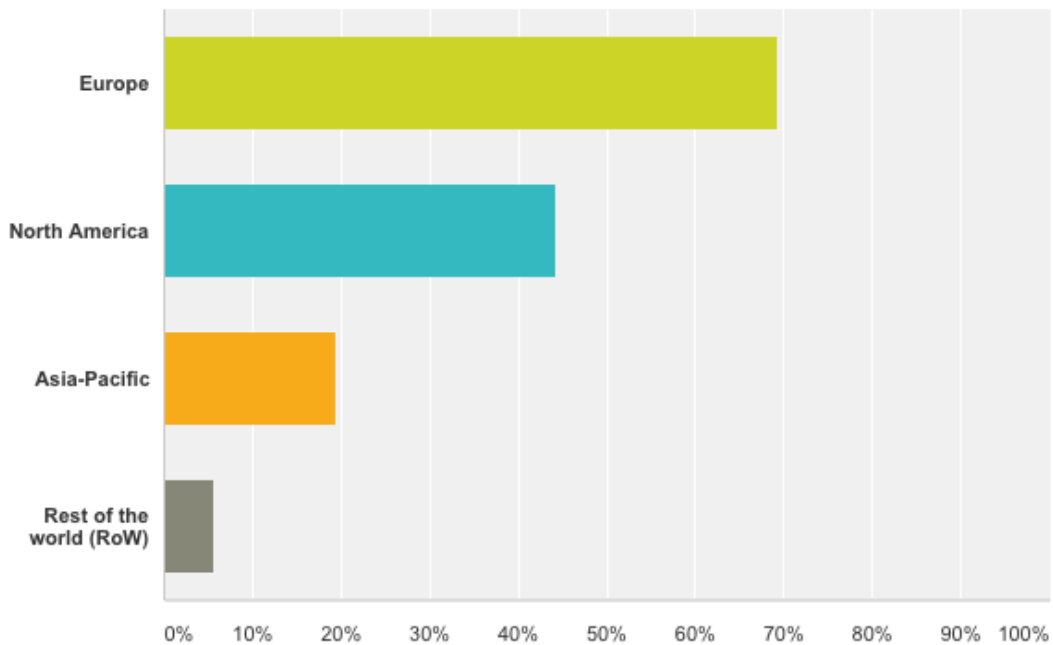
- The vast majority of responders were regulatory medical writers (88%) followed by publication (36%) and medical communications writers (30%); 9% were involved in posting results and 9% in clinical trial disclosure; 6% were regulatory affairs professionals
- Contract research originations were the most common employers (42%), followed by large pharma (18%) and small pharma or biotech companies (19%); 17% of responders were freelancers and 3% were academics

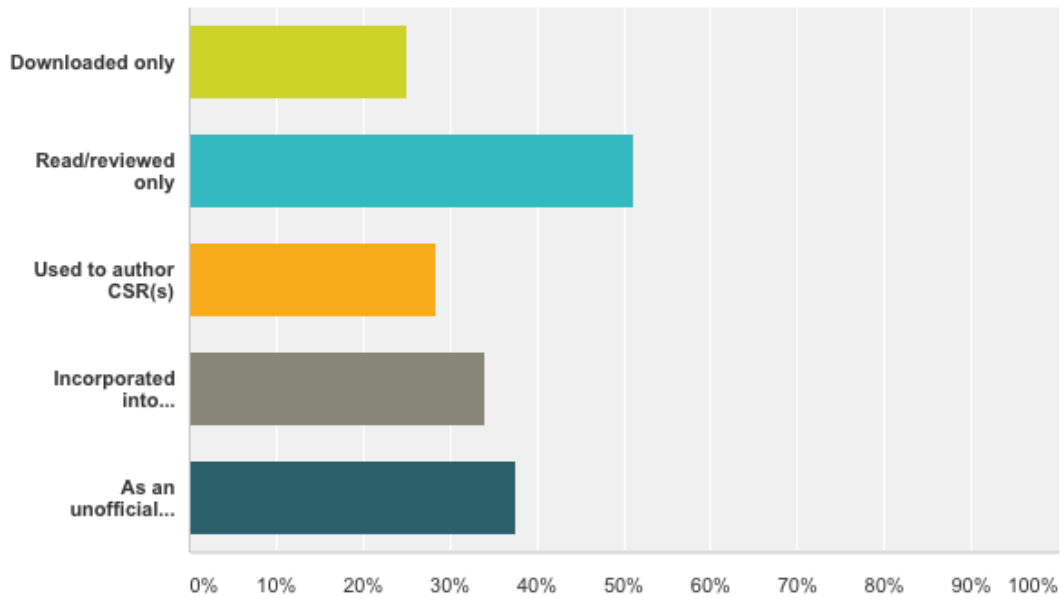Figure 1: WHAT TYPE OF ORGANISATION DO YOU WORK FOR?

- Responders' clients were mostly based in Europe and North America (60% and 44% of responders, respectively); 19% reported their primary client location as Asia-Pacific; 6% reported clients based in other locations (Latin America, Israel and Australia)

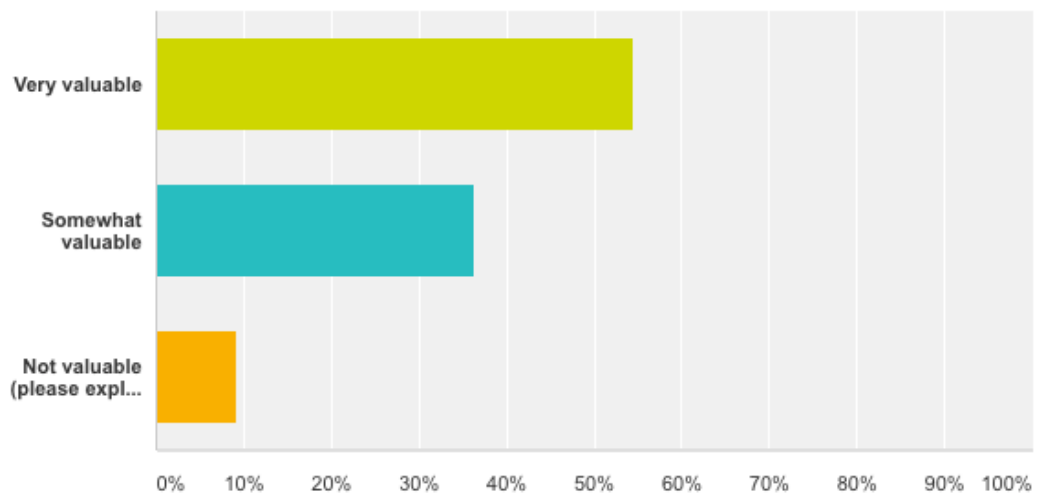Figure 2: WHERE ARE YOUR PRIMARY CLIENT LOCATION(S)

- When asked about the use of CORE Reference to date, 37% of responders had used it as an unofficial reference tool, 34% had incorporated it into their procedures, policies and/or templates and 28% had used it to author clinical study reports (CSRs)

Figure 3: HOW HAVE YOU USED CORE REFERENCE TO DATE?

- Finally, 80% of users found CORE Reference to be very or somewhat valuable (48% and 31%, respectively); just over half (52%) had signed up to the CORE Reference mailing list.

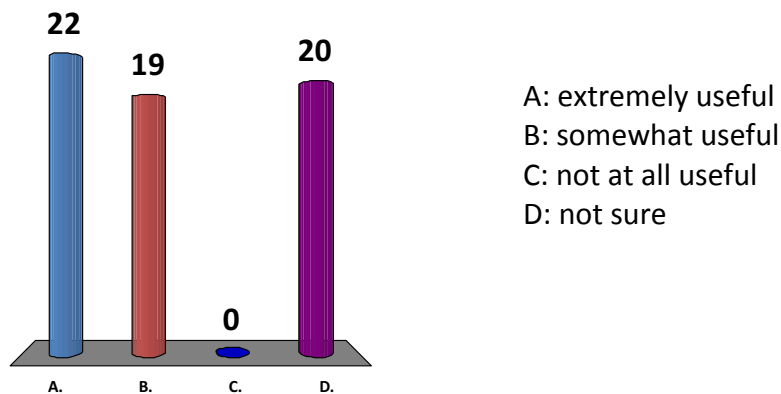Figure 4: WHAT VALUE DO YOU ASSOCIATE WITH CORE REFERENCE?

Tracy shared the podium with Sam Hamilton who explained the relationship between CORE Reference and public disclosure of CSRs. Sam reiterated that CORE Reference is a complete and authoritative open access resource for authoring CSRs for interventional studies fit for today's public disclosure environment. She proposed that "smart authoring" of the regulatory review version CSR - that incorporates proactive anonymisation of sensitive data - maintains high data utility whilst minimising the need for redactions in the public disclosure version CSR. Sam explained how CORE Reference highlights hotspots in the CSR where sensitive information may need to be safeguarded in line with European Medicines Agency Policy 0070, and includes links to relevant guidances, making it an all-inclusive resource.

At the start of the presentation, Sam asked audience members to rate their perception of the usefulness of CORE Reference in preparing CSRs fit for public disclosure, based on their understanding of the resource. Similar numbers responded 'A: extremely useful', 'B: somewhat useful' or 'D: not sure'. No audience member considered CORE Reference to be 'C: not at all useful' at the start of the presentation.

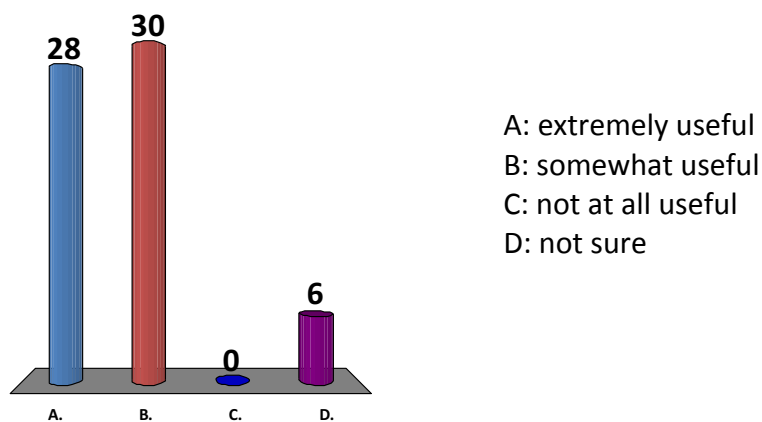Figure 5: QUESTION TO AUDIENCE AT THE START OF THE CORE REFERENCE PRESENTATION
Based on your current understanding of CORE Reference, how useful do you think it would be in preparing CSRs fit for public disclosure?

A: extremely useful
B: somewhat useful
C: not at all useful
D: not sure

When Tracy repeated the same poll after she and Sam had presented the Utility Survey results and instructive information on CORE Reference, all audience responders except for 6 who remained unsure, felt that CORE Reference was extremely or somewhat useful in the context of preparing CSRs fit for public disclosure.

Figure 6: QUESTION TO AUDIENCE AT THE END OF THE CORE REFERENCE PRESENTATION
Now that you have gained some familiarity with CORE Reference, how useful a resource do you consider it in preparing disclosure-ready CSRs?

A: extremely useful
B: somewhat useful
C: not at all useful
D: not sure

The audience's improved understanding highlighted the importance of continuing to engage with colleagues to raise awareness about the general utility potential of

CORE Reference, not least in supporting CSR-related public disclosure requirements.

Please continue to tell us about your use of CORE Reference via www.core-reference.org/adoption-and-use. We know from your personal contact with us that support is widespread, but we need your public declaration of support on the website. Thank you.

This article was written with the support of Tania Kotsokechagia, Lexis Communications Ltd.

Sam Hamilton
Chair http://www.core-reference.org