CORE Reference - One Year On
Clarity and Openness in Reporting: E3-based

Sam Hamilton and Tracy Farrow for

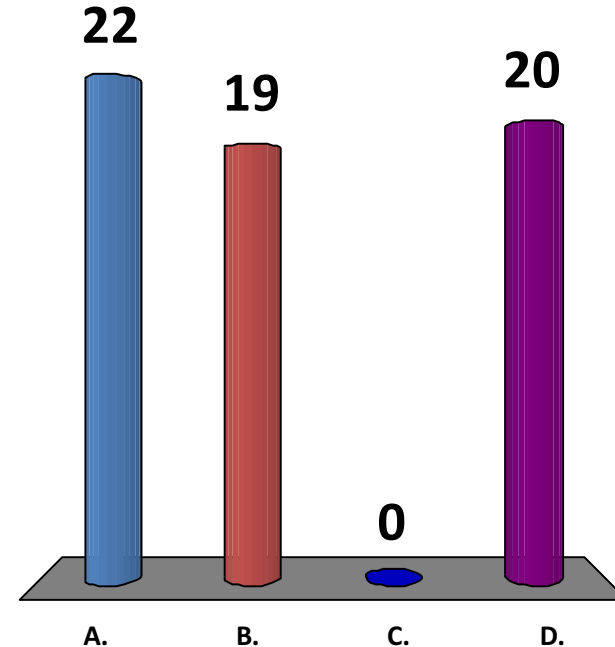Budapest Working Group:
Developer of CORE Reference

5th EMWA Symposium 04 May 2017
Transparency and Disclosure of Clinical Regulatory Documentation

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

[question to audience before presentation]

22

19

20

0

A.   B.   C.   D.

EUROPEAN MEDICAL WRITERS ASSOCIATION

CORE Reference & Disclosure

1. CORE Reference

— **Preface** (21 pages, references + assumptions, including "public disclosure")

— **Main body text** (103 pages)

- ICH (E3 and 2012 Q&A) guidance text
- EU and US regional guidances including "public disclosure"
- CORE Reference text with explanatory comments
  - Including "public disclosure" awareness comments: colour-coded PPD and CCI

2. Mapping document

— ICH E3 ⬅ mapping ➡ CORE Reference sectional structure

3. Explanation and elaboration paper including "public disclosure

Hamilton S, et al Research Integrity and Peer Review 2016

Web-based User Manual

http://www.core-reference.org

LIVE TOUR

— **Disclosure-related content**

— **New content**

SMART AUTHORING

- PPD and CCI awareness comments:
"Discussion" excerpt

CORE Reference should therefore not only expedite the move towards EMA's intended goal of a heavily 'proactive approach' to anonymisation but may also contribute to increased trust derived from this approach, which should reduce the need for piecemeal redaction of individual words and phrases throughout a document.

In addition, time, money and cost savings in the development of CSRs for their primary and secondary uses should be possible [8].

Hamilton et al, *Research Integrity and Peer Review* 2016

MONITORING USE

"Discussion" excerpt

The website is fitted with separate download counters for CORE Reference and the mapping tool. Although this will enable us to monitor resource downloads, it is less easy to monitor the use of CORE Reference in practice. We therefore encourage user feedback via both a 'Contact' and a 'Support' page.

Hamilton et al, *Research Integrity and Peer Review* 2016

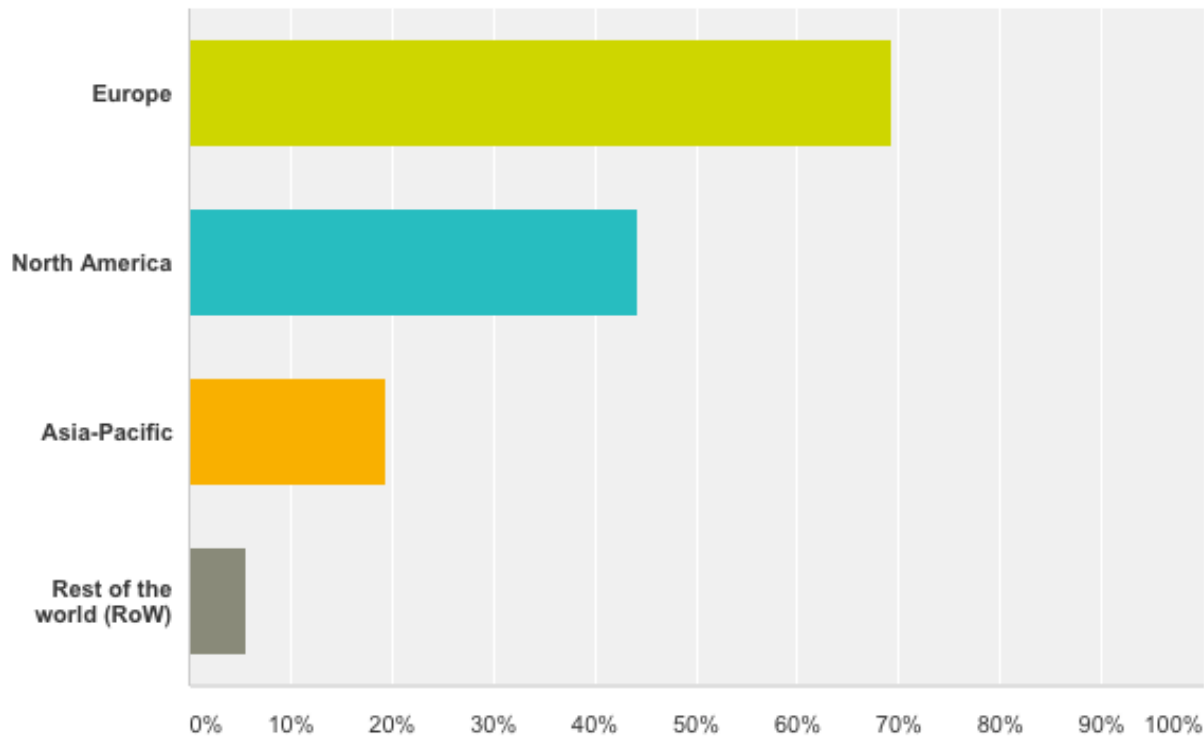# ONE YEAR ON: CORE REFERENCE UTILITY SURVEY
22 MARCH – 21 APRIL 2017

UTILITY SURVEY RESULTS

- Open for one month

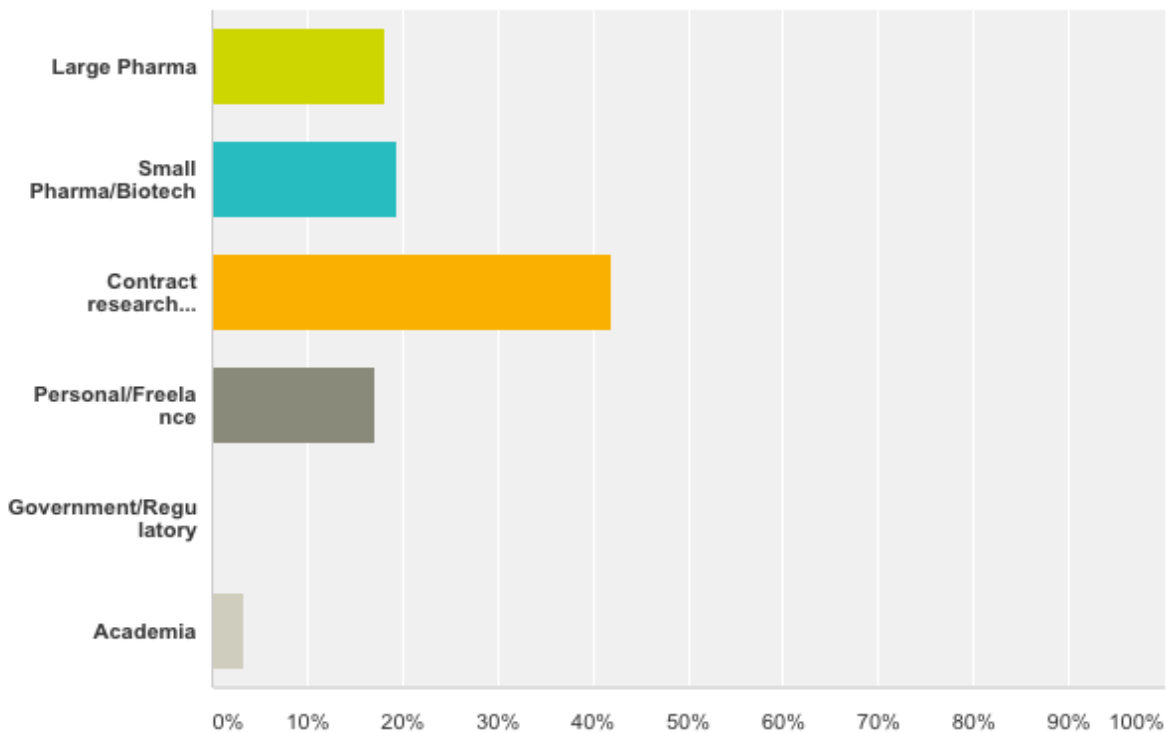- Closed 21 April 2017

- First presentation of results today

WHERE ARE YOUR PRIMARY CLIENT LOCATION(S)?
(SELECT ALL THAT APPLY)

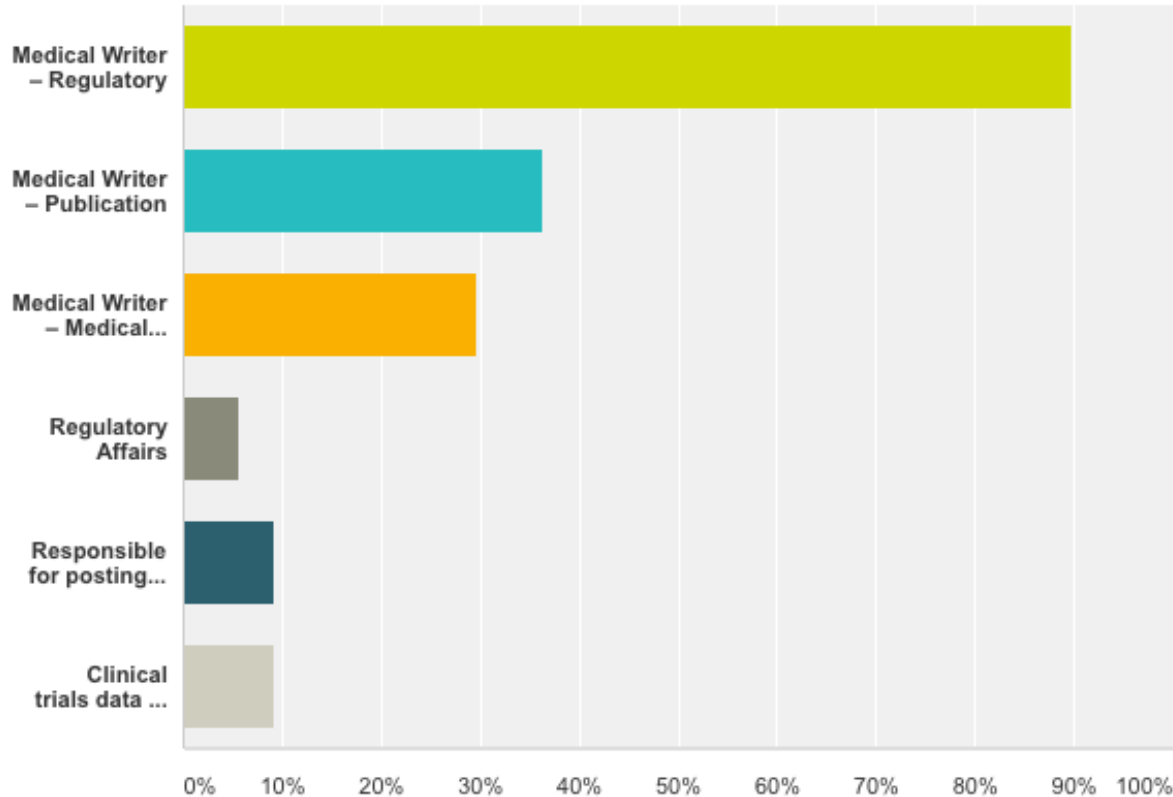| Answer Choices	Responses
Europe	69.32% (61)
North America	44.32% (39)
Asia-Pacific	19.32% (17)
Rest of the world	5.68% (5)
Total Respondents: 88; Answered: 88; Skipped: 0	

ROW: rest of the world; responses included Latin America, Australia and Israel
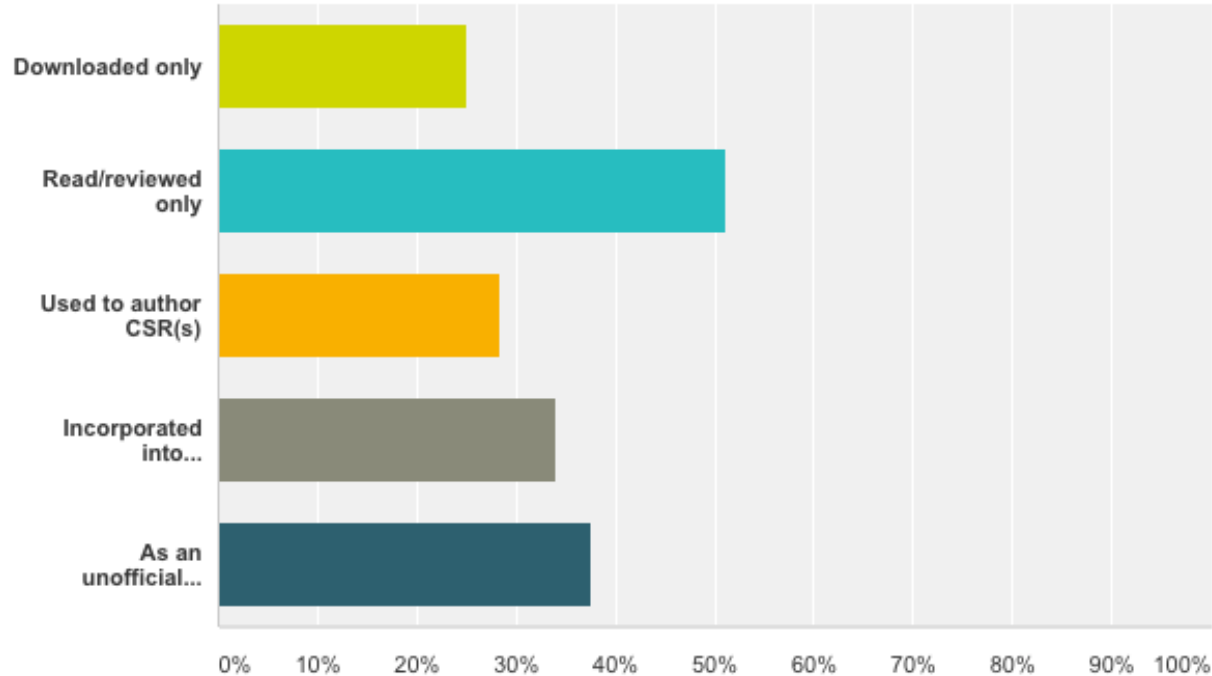
WHAT TYPE OF ORGANIZATION DO YOU WORK FOR?

Answer Choices	Responses
Large Pharma	18.18% (16)
Small Pharma/Biotech	19.32% (17)
Contract research organization (CRO)	42.05% (37)
Personal/Freelance	17.05% (15)
Government/Regulatory	0.00% (0)
Academia	3.41% (3)
Total Respondents: 88; Answered: 88; Skipped: 0	

WHAT IS YOUR ROLE? (SELECT ALL THAT APPLY)
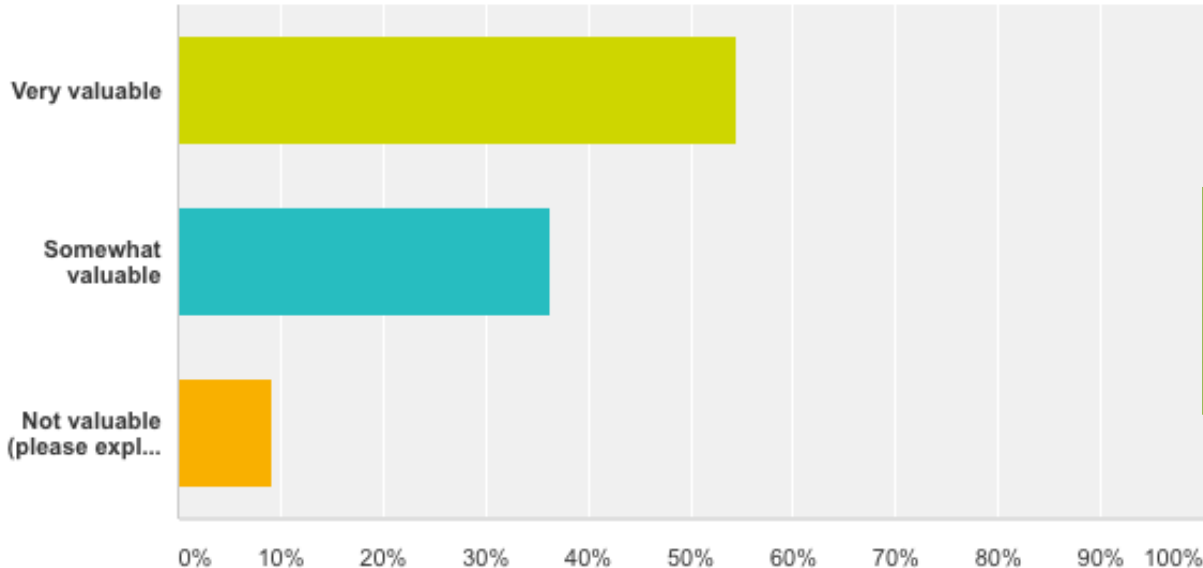

Answer Choices	Responses
Medical Writer - Regulatory	89.77% (79)
Medical Writer - Publication	36.36% (32)
Medical Writer - Medical	29.55% (26)
Regulatory Affairs	5.68% (5)
Responsible for posting results	9.09% (8)
Clinical trials data – public disclosure and transparency	9.09% (8)
Total Respondents: 88; Answered: 88; Skipped: 0	

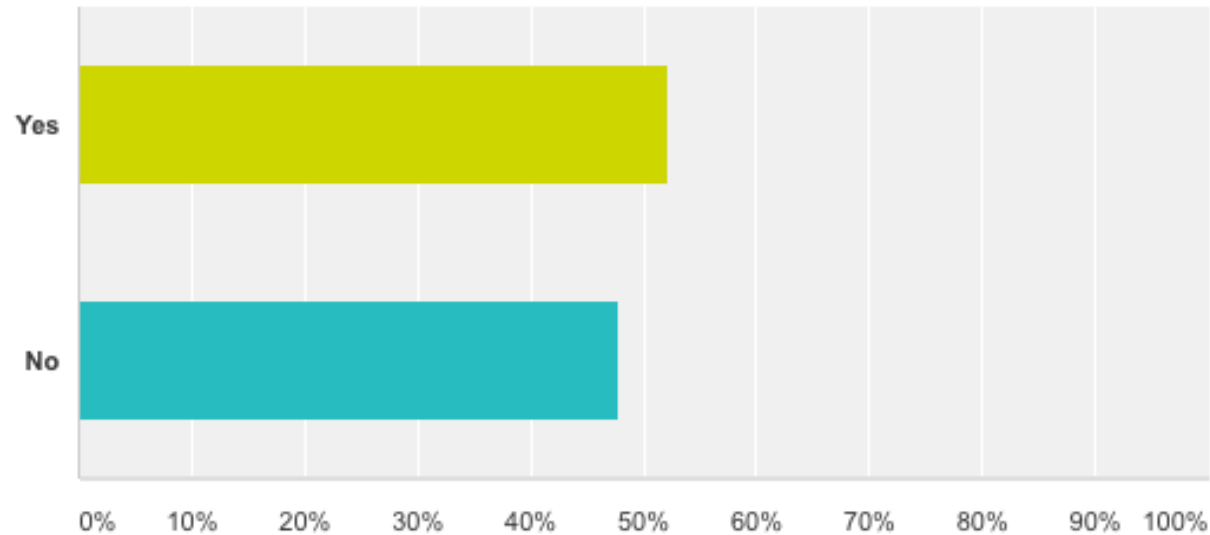# HOW HAVE YOU USED CORE REFERENCE TO DATE?
(SELECT ALL THAT APPLY)

Answer Choices	Responses
Downloaded only	25.00% (22)
Read/reviewed only	51.14% (45)
Used to author CSR(s)	28.41% (25)
Incorporated into SOPs/ policies/templates	34.09% (30)
As an unofficial reference tool	37.50% (33)
Total Respondents: 88; Answered: 88; Skipped: 0	

WHAT VALUE DO YOU ASSOCIATE WITH CORE REFERENCE? DO YOU FIND IT:

Answer Choices	Responses
Very valuable	54.55% (48)
Somewhat valuable	36.36% (32)
Not valuable	9.09% (8)
Total Respondents: 88; Answered: 88; Skipped: 0	

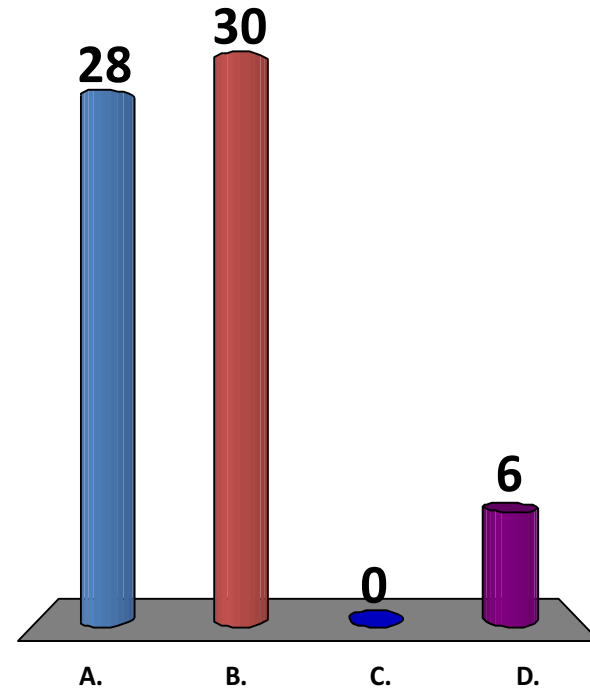# HAVE YOU SIGNED UP TO THE CORE REFERENCE MAILING LIST ON WWW.CORE-REFERENCE.ORG?

Answer Choices	Responses
Yes	52.27% (46)
No	47.73% (42)
Total Respondents: 88; Answered: 88; Skipped: 0	

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

[question to audience following presentation]

THANK YOU