DIA 2014 50th Annual Meeting

Celebrate the Past – Invent the Future

June 15 – 19, San Diego (CA) Convention Center

Session 129— *Regulatory Submissions: Better, Faster, and Cheaper*

Regulatory Submissions: Better, Faster, and Cheaper provided an overview on medical writing techniques, with speakers offering strategies for submitting high-quality clinical documents for a new drug application or biologics license application on time and within budget.

Dr. Anita Frijhoff (Senior Writer, Randstad Pharma) identified the three main challenges of medical writing: Limited upfront content delivered by the client, a request for new analysis received at the pre-NDA sponsor-FDA meeting, and sometimes understaffed and apathetic teams.

Dr. Nancy Katz (President & Principal Medical Writing Consultant, Illyria Consulting Group) shared the results of a survey conducted to investigate the time spent on duties related to writing the clinical study report (CSR). The amount of extra hours spent on tasks associated with writing the CSR is almost unimaginable!

Dr. Frijhoff, Dr. Katz, and Dr. Marijke Adams (President & Principal Scientist, MH Adams & Associates, Inc.) explained how to leverage software to reduce workloads without impacting delivery of high-quality medical writing and related documents.

They specifically introduced three simple but useful software programs for coping with lengthy documents, and provided recommendations on how to form a high-efficiency submission writing team and how to implement strategies that minimize additional hours for your CSR writer.

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