Celgene History Book: An Innovative and Interactive Key Publication **Archiving Tool**

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ABSTRACT

Objective: Over the years, the number of clinical trials with Celgene products has increased drastically leading to more requests for published material from various departments. Internally, there were several sites where abstracts, posters, oral presentations, and manuscripts were archived, however there was no tool providing a chronological overview and quick access to all material.

Methods: Various cross-functional teams from Global Medical & Scientific Communications collaborated to develop a History Book, to classify publications. Key clinical trials were identified and labeled with a consistent taxonomy in a bibliographic style. All publications were organized in an electronic PDF format, and hyperlinked to trial websites and internal databases. Results: Six disease History Books were developed and published in 2012 detailing 24 trials and covering more than 627 citations. After 6 months of usage, a survey was sent to all users (N=423 from 30 countries), and demonstrated high utilization and satisfaction ratings across departments including medical, clinical, legal, regulatory and drug safety. Awareness and availability of the tool was communicated via corporate e-mails and internal portal alerts. Conclusion: The History Books successfully addressed a previously unmet need, and provided a permanent, up-to-date, resource accessible to various cross functional teams. In addition, this

innovative tool has been very popular and frequently used when on boarding new colleagues.

BACKGROUND

More information will be presented at the meeting.

- The Celgene Global Medical and Scientific Communications team recognized the unmet need for comprehensive lists of publications associated with key trials when frequent requests emerged from internal customers
- There were no centralized trial publication lists available globally, no process for routine updates, and it was difficult to identify all appropriate records
- Clinical trial identifiers were not routinely incorporated into the publication record and our bibliographic tool had no searchable field to accommodate internal and ClinicalTrials.gov trial ID numbers
- Trial subanalyses were particularly difficult to link clearly to a primary study
- Team members expended valuable time searching both internal and external sources to generate custom responses on an ad hoc basis. There was no formal way to share this knowledge

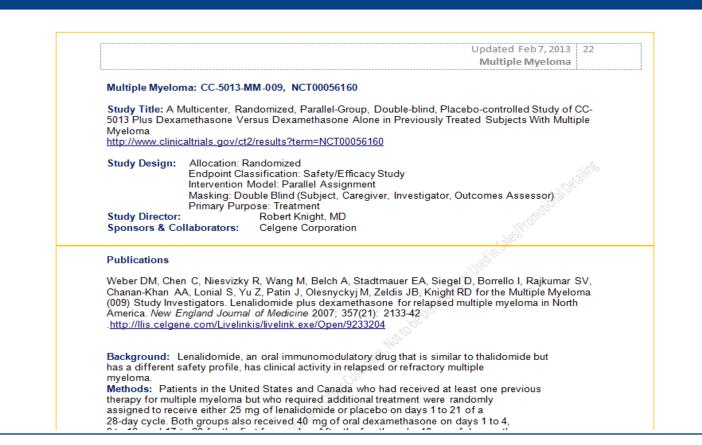
AIM

- To retrospectively and proactively identify all abstracts and journal publications associated with key trials
- To provide readily accessible, searchable, up-to-date information in the Celgene library
- To implement a process to preserve each trial's publication legacy in a History Book (disease-related repository)

Figure 1. 6 Therapeutic Teams —6 History Books



Figure 2. Inside the History Book: Hyperlinked ToC, Trial Overview, **Subanalyses**



METHODS

- Disease-centric cross-functional teams were formed from the 3 departments: Knowledge Center, Medical Information, and Scientific Communications
- Each therapeutic team selected the key trials, researched synonyms, and followed a rigorous quality control process
- Trial identifier fields were added to both the existing bibliographic tool and the new library search engine to accommodate all the trial identifiers
 - eg, Celgene internal number, NCT, EudraCT, and other synonyms listed on ClinicalTrials.gov
- The team disease experts searched both internal and external databases to identify relevant publications and determined if any additional categories or subanalysis labels were appropriate
- Hyperlinked citations were organized by trial and listed chronologically, with the seminal or most recent citation appearing first, clearly delineating the publication history
- Processes for ongoing History Book updates were defined, including the strategy for trial selection and a communication plan
- Surveys were created to gather feedback from users and team members to guide future development

RESULTS

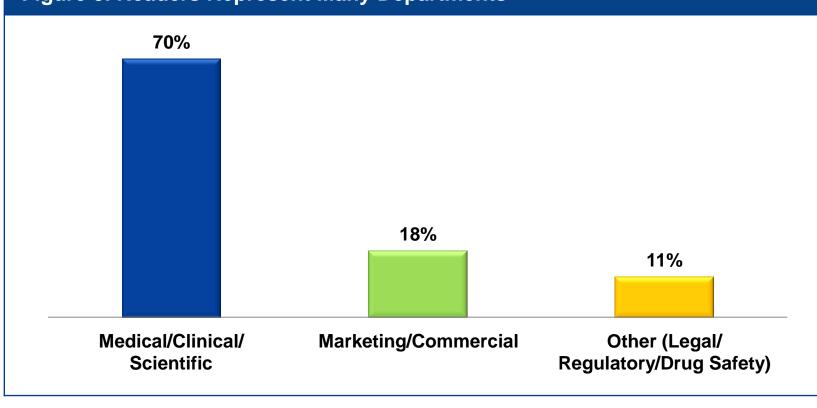
- The first History Book was published in May 2012
 - Currently 6 History Books are available online Detailing 24 trials, with over 700 citations
 - Viewed over 1200 times by affiliates worldwide
 - Readership included Medical Affairs, as well as other departments such as Legal,

Regulatory, and Drug Safety

RESULTS (cont)

- Searchable by trial, category, and subanalysis
- A survey was conducted at the end of 2012
- Readers reported high utilization and satisfaction
 - Comments were universally positive
 - 65% stated that information in the History Books was directly relevant to their job function

Figure 3. Readers Represent Many Departments

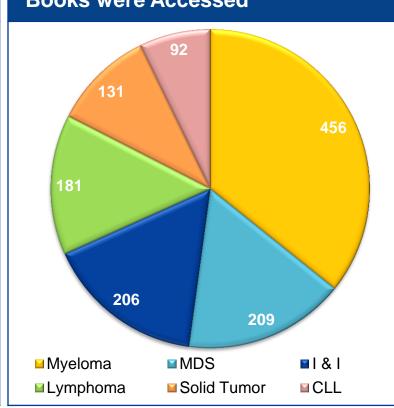


- Two overarching themes of user feedback relevant to job function:
 - Easy reference or educational resource
 - Unique applications
 - Developing open research questions
 - Assisting with reimbursement submissions
 - Aiding in identifying trial subanalyses
 - Identifying different subpopulations in the publications
 - Training new employees or those changing job focus
 - Developing presentations
 - Intellectual property or patent searching
 - User recommendations for future enhancements:
 - Further details: Tables, study design, and contextual background about each trial
 - Additional trials: More indications, additional study types (investigator initiated trials or competitor trials)
 - Easier access and navigation, real-time updates
- Where feasible, improvements are being incorporated:
 - Expanded number of studies

New format for better navigation

Figure 4. History Book Utilization by Region 46% ■ Eastern Europe ■ Asia/Pacific ■Nordic ■US/Canada

Figure 5. Number of Times History Books were Accessed



I & I, Immunology and Inflammation. Figure 6. Global Readership From 30 Different Countries

Australia, Austria, Belgium, Canada, China, Czech Republic, Denmark, France, Germany, Greece, Hong Kong, Hungary, Italy, Japan, Korea, the Netherlands, Norway, Poland, Portugal, Russia, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Taiwan, Turkey, UK, and **USA**

LIMITATIONS OF THE HISTORY BOOKS

- For this project, an expert panel in each therapeutic team chose a limited number of trials to include in the initial History Books
- There were practical limits of time and resources to meet disparate geographical and departmental needs
- The relatively modest response rate to the user survey prevents a full assessment of the true value of the project

CONCLUSIONS

- The History Book initiative successfully addressed an unmet need, was well received, and was utilized globally
- History Books have been adopted and recognized as a best practice within our company
- The process preserved trial histories as a permanent part of the publication record
- Cross-functional collaboration fostered teamwork and an invaluable team experience

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