Types of writing in clinical research

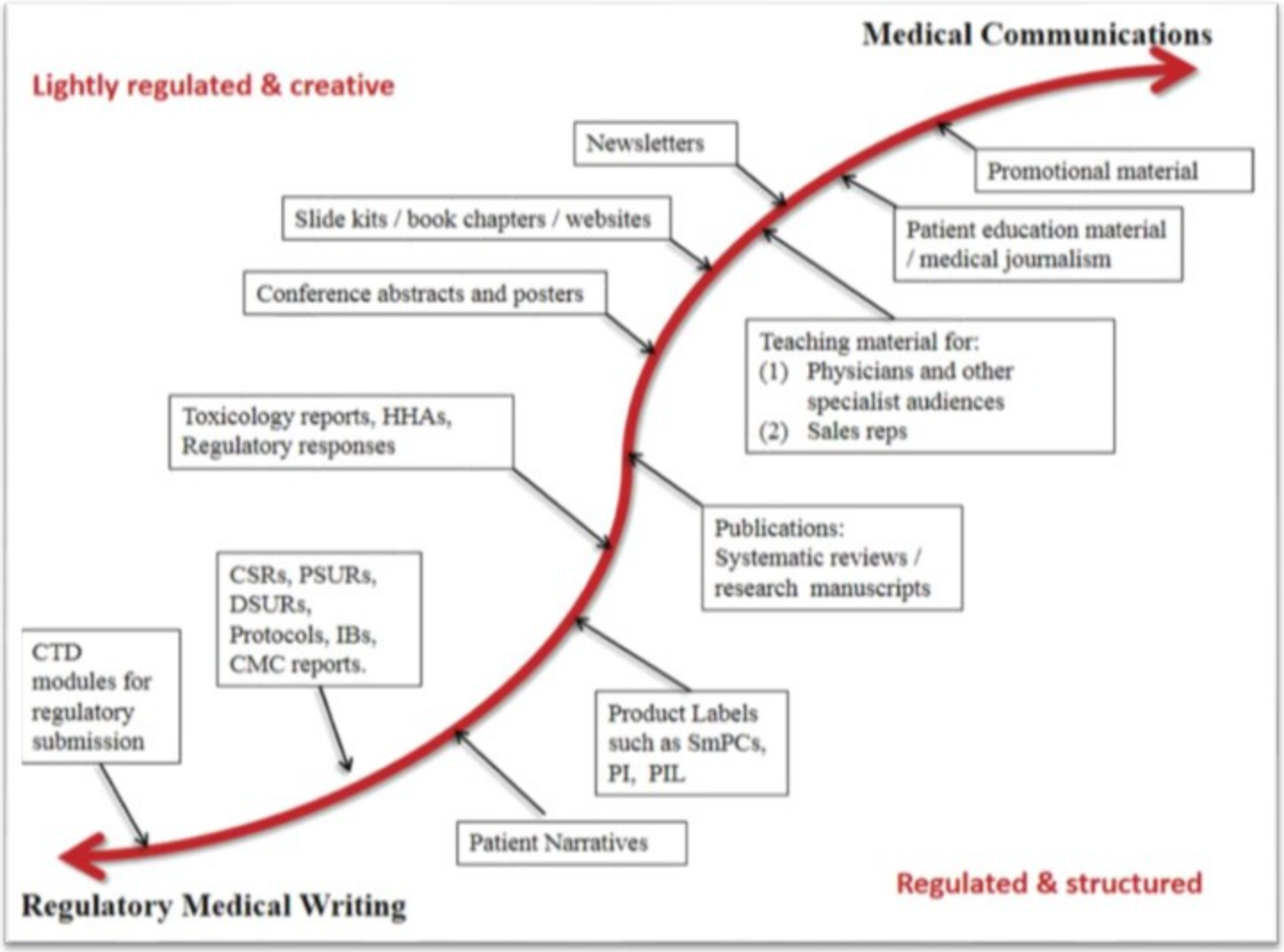
Module 11 Topic 4

Medical Writing

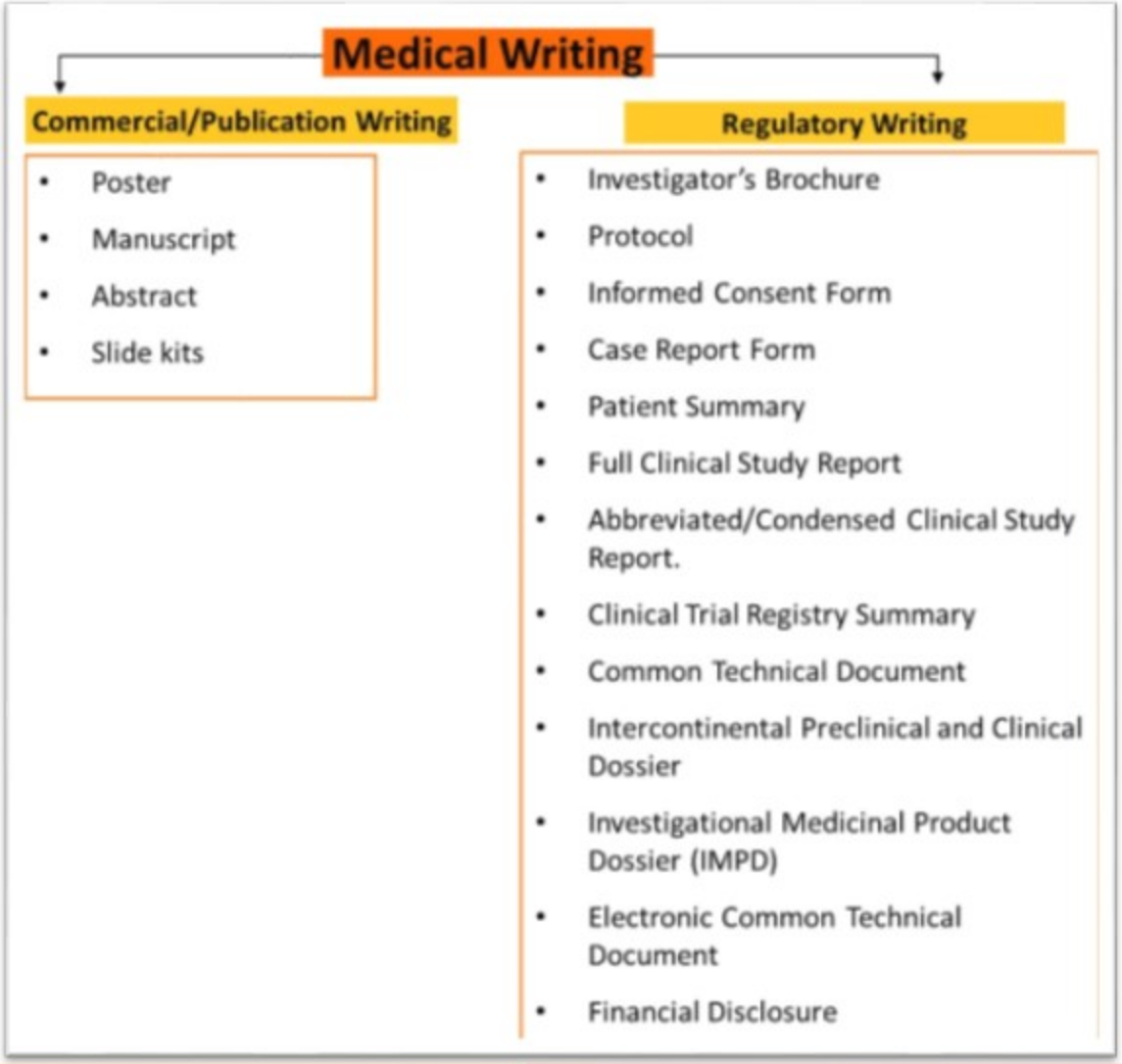
- Medical writing is an activity of writing scientific documentation by someone who is a specialized writer (a medical writer) and is generally not one of the scientists or doctors who performed the research
- Purpose - A writing specialist works together with the people who produce the scientific data, in order to create documents that effectively and clearly express the messages (that the data has to tell)
- The medical writer also serves to make sure that the documents comply with any regulatory, journal or other guidelines in terms of content, format and structure

Types of medical writing (major classification)

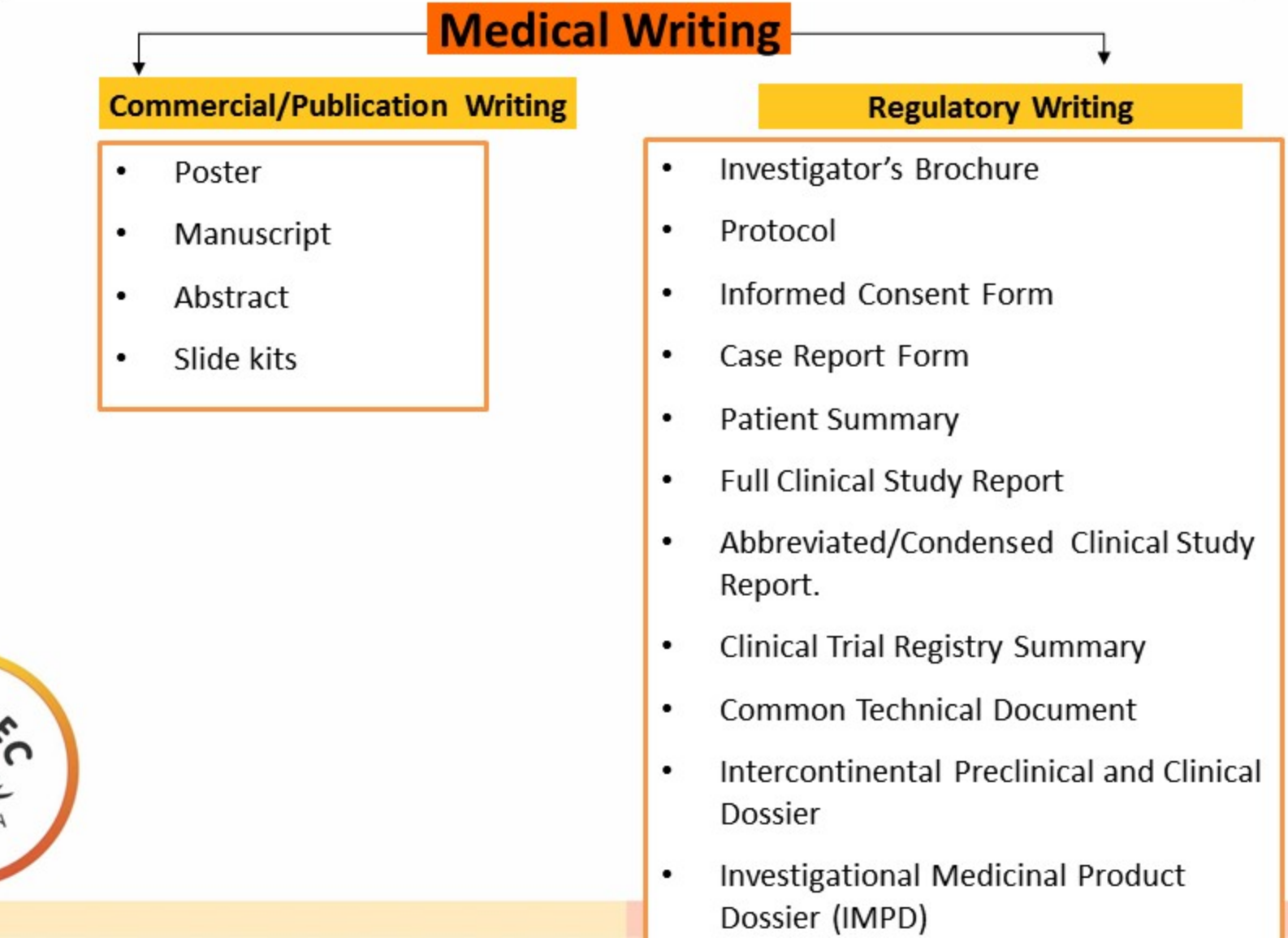
- Regulatory Writing
- Commercial Writing


Medical Communications
Lightly regulated & creative
Newsletters
Promotional material
Slide kits / book chapters / websites
Patient education material / medical journalism
Conference abstracts and posters
Teaching material for:
(1) Physicians and other specialist audiences
(2) Sales reps
Toxicology reports, HHAs, Regulatory responses
Publications: Systematic reviews / research manuscripts
CSRs, PSURs, DSURs, Protocols, IBs, CMC reports.
CTD modules for regulatory submission
Product Labels such as SmPCs, PI, PIL
Patient Narratives
Regulated & structured
Regulatory Medical Writing

Medical Writing-Classification



Medical Writing-Classification



COMPARISON OF REGULATORY WRITING AND PUBLICATION WRITING

	Regulatory Writing	Publications
Types of documents	Clinical study reports Protocols Investigator brochures Other IND/NDA sections FDA briefing packages Informed consent forms *[See a sample protocol and a protocol template at http://www.med.upenn.edu/ohr/protocol/]*	Journal manuscripts • Review articles • Clinical trial reports • Other biomedical research studies • Pharmacoeconomic studies Conference abstracts, posters, and oral presentations Publication plans Slide kits
Types of companies	Pharmaceutical Biotechnology and device companies Freelancers Contract Research Organizations	Pharmaceutical Biotechnology and device companies Freelancers Medical communications agencies
Main writing goals	Clarity, accuracy, completeness, consistency	Clarity, accuracy, conciseness, clinical relevance
Primary audiences	FDA reviewers, study investigators, and staff	Clinicians, scientists
Nature of the writing	Very long, highly structured documents Exhaustive presentation of data and procedures Keep interpretation "close to the data" Documents are small sections of larger documents Big emphasis on formatting, use of styles, document management Close connection to "publishing" steps Less literature work Confidentiality	Short documents Narrow, selective presentation of data and methods Emphasize clinical relevance rather than report everything More summarization, synthesis, interpretation Connection to current literature is critical Delivery of simple MSWord documents Style dictated by journal or conference Format less important

Source: AMWA CAROLINAS DINNER DISCUSSION, Presented by Ellen Stoltzfus 12 November 2009

DESCRIPTIONS OF A TYPICAL PROJECTS FOR REGULATORY AND PUBLICATIONS WRITERS

Regulatory Writing: Clinical Study Report	Publications: Clinical Trial Manuscript
1. Meet with team for months before start writing 2. Write "shell" methods and tables based on protocol and statistical analysis plan • Use client template as guide to content of each section • Copy and paste large sections from other documents; adapt for clarity, continuity, consistency, tense, and format • Anticipate tables for the results section and build them • Gather missing information from clinical, medical, biostats teams • QC and other internal review 3. Possibly have review meeting with entire team 4. Incorporate comments from many different people on the team (shell review may be smaller team) 5. Receive topline tables and review with client 6. Receive final tables 7. Complete first draft (takes about 3 weeks for the writing) • Fill in shell tables with data • Spend long hours with SAS tables • Write very short discussion section and very long results • Describe all efficacy measures, usually in great detail • Write in standard ways about safety data (esp. adverse events) • Describe other safety results specific to the drug/indication/population/study • Details on individual patients with bad safety outcomes • QC and other internal review 8. Team review meeting or receive e-comments (medical monitor, biostatistics, senior review, regulatory, clinical operations) • Comments usually integrated 9. Incorporate 1-3 review cycles of comments from large teams • Formal drafts • Review cycles with hard and fast timelines	1. Meet with authors/team to discuss key points and data to be included 2. Receive key tables or extract them from a CSR 3. Draft an outline with tables and figures 4. Receive and incorporate comments and draft extended outline (or proceed to first draft) 5. Write first draft • Only relevant aspects of methods and results • Focus on group data • Summarize, be concise, keep under word limits • Connect research question and data to literature • Work with authors, editorial manager, statistician to get missing information • Copyedit and format for journal's guidelines 6. Receive and incorporate comments from authors and other team members • Authors have final say • Comments never integrated 7. Do 2-8 more rounds of revisions • May be heavy or light revision • May be different reviewers at each step • Reviews stop when the authors/team decide they are done (or budget runs out) • Soft deadlines that are hard to enforce

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Regulatory

- Clinical trial protocols
- Investigators brochure and updates
  Regulatory documents
  - Clinical Study Reports (Phase IIV)
    Integrate safety summaries
- Patient narratives
  Policy documents
- Submissions (investigational new drug application)
  IND and NDA annual reports, amendments, supplements
- Advisory committee preparation
  - FDA advisor briefing book

Publication writing

Manuscripts

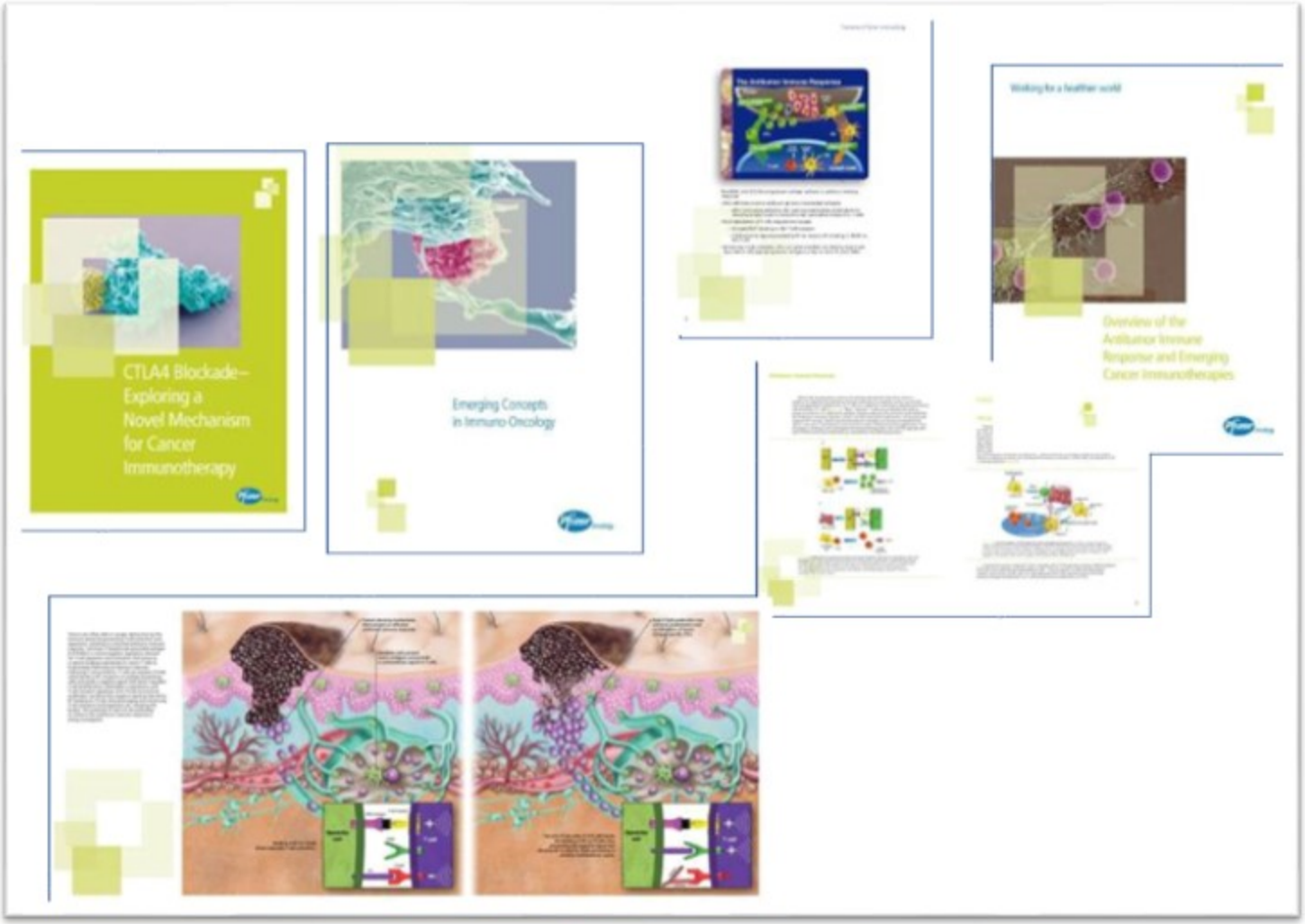
Congress activities

- Abstracts
- Posters
- Oral presentations
- Booth materials

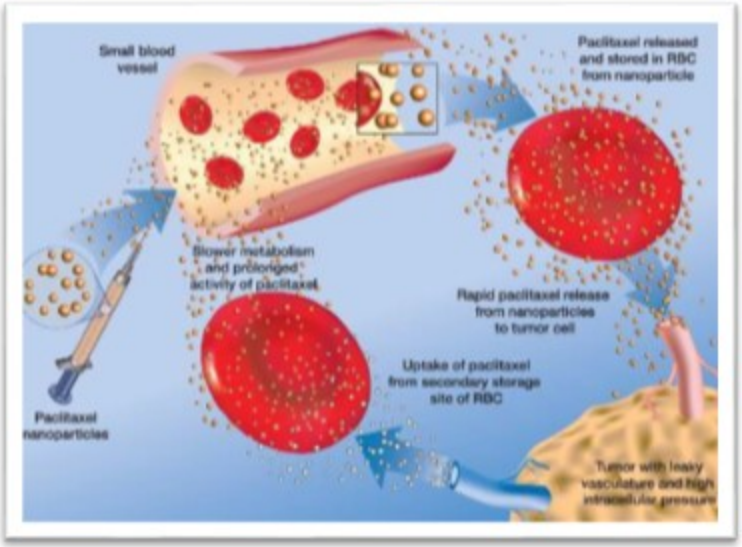
Supportive Publications Services

- Strategic literature analyses
- Congress intelligence
- Ad hoc scientific analyses
- Interactive CD-ROM bibliography
- Supplements
- White papers

Booth Collaterals



Illustration

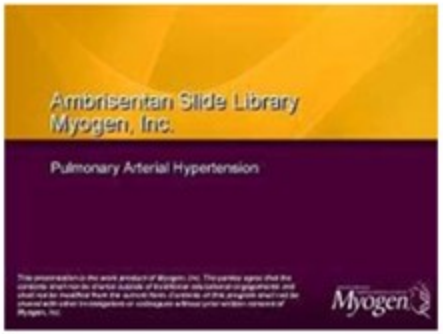


Medical Education

- Corporate-sponsored symposia at medical congresses
- Speaker training
- Speaker bureau
- Slide libraries
- Website content
  - Key opinion leader portals
- Monographs

Education Materials

Slide Libraries



Web Portals

Pharmaceutical Company Training and Information Services

- Sales representative training manuals Medical science liasion (MSL) materials
  - Training
  - Physician education
  - Question and answer documents
- Reference libraries

Training Materials

Oncology Learning System

Promotion

- Newsletters
- Patient education materials
  Public relations materials
- Advertising copy for pharmaceuticals and other products
- Internet content
  CDs
- Magazine articles - popular press
  Detail aids
- Launch materials