

# Roles and responsibilities



Module 10 Topic 1

# What is Medical Writing?

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“**Medical writing** is the 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 whose research it was.”



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- Medical writing is about communicating clinical & scientific data & information to a range of audiences in a wide variety of different formats
  - Medical writers (MWs) combine their knowledge of science & their research skills with an understanding of how to present information & pitch it at the right level for the intended audience



# Examples of Medical Writing

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- Journal articles
  - Original research
  - Review articles
  - Editorials, case reports, etc.
- Abstracts
  - Publication in journals
  - Submission to medical meetings
- Posters
  - Presentation at medical meetings



# Examples of Medical Writing (contd)

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- Slide presentations
  - Original research
  - Symposia
  - Roundtables
  - Advisory boards
- Medical education materials
  - Monographs
  - Training materials
  - Prescribing information



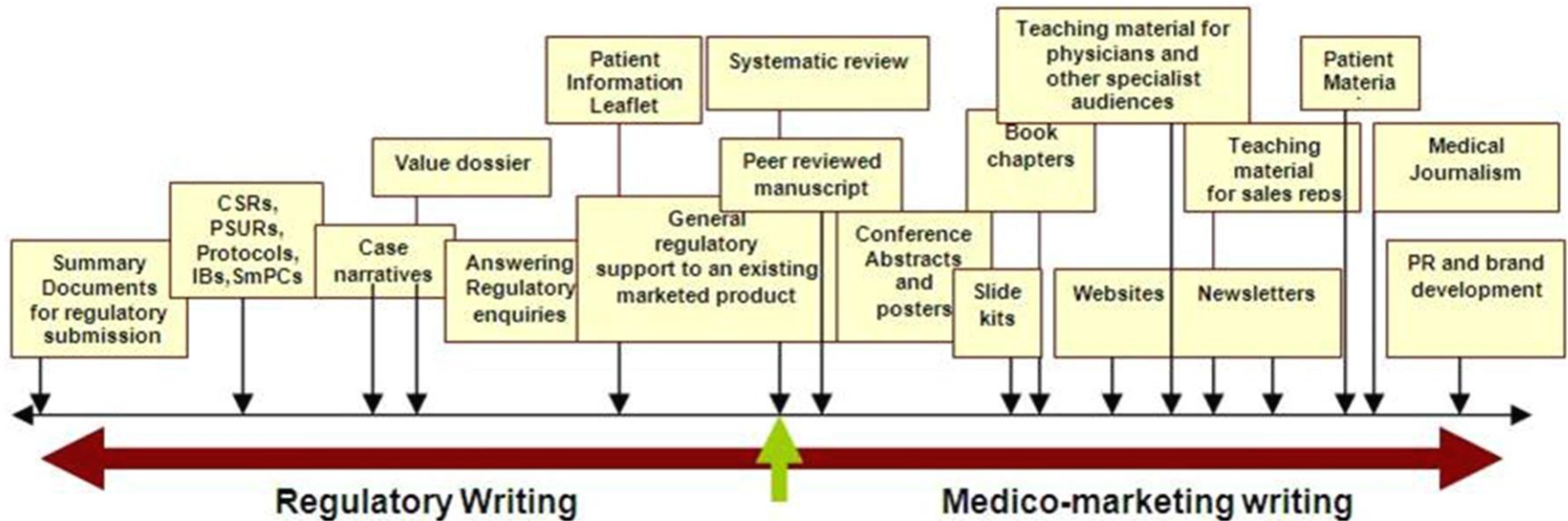
# Examples of Medical Writing (contd)

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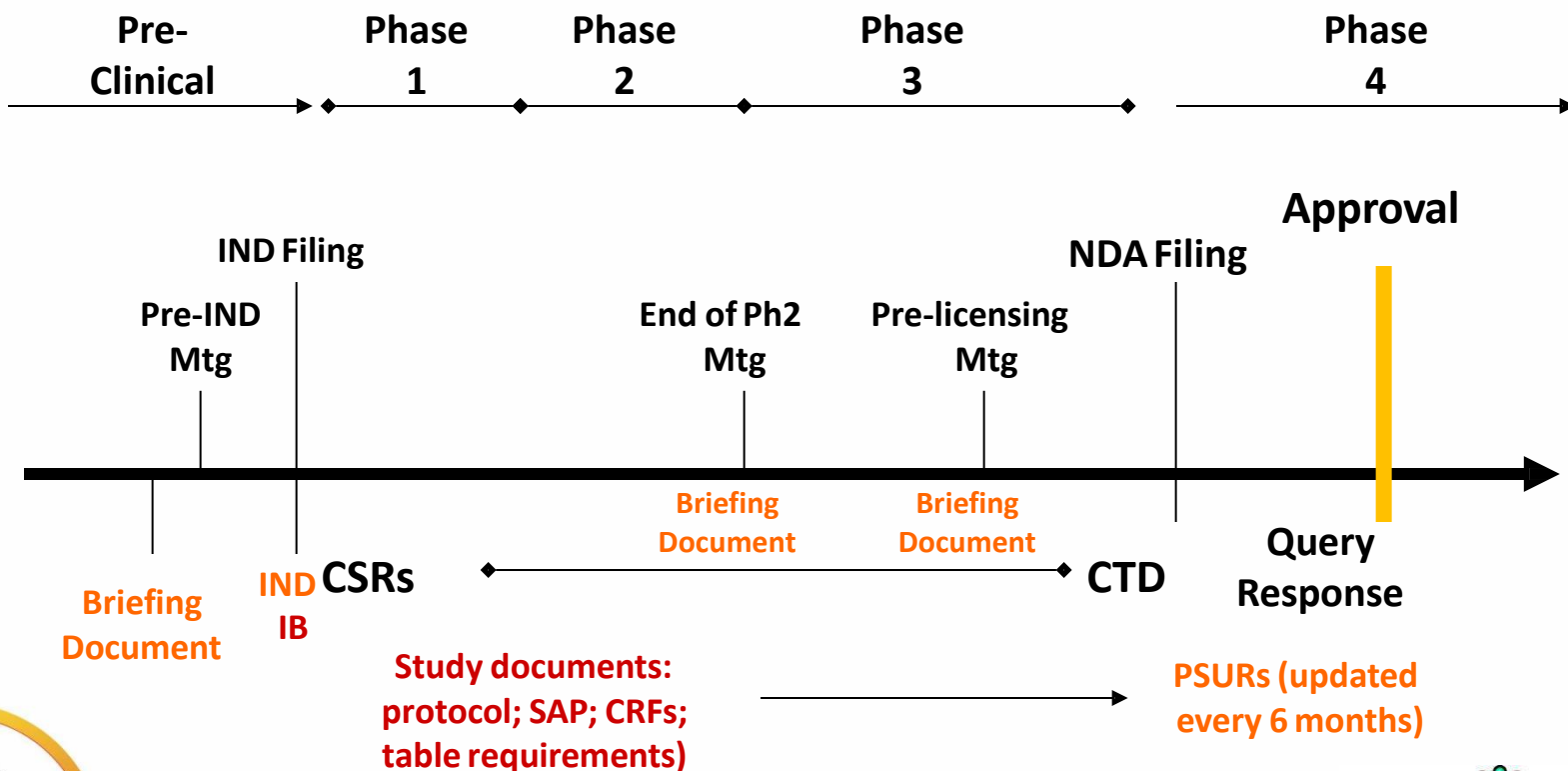
- Regulatory documents
  - Clinical Trial Reports (CTR)
  - New Drug Applications (NDA)
  - Investigational New Drug Application (IND)
- Marketing materials
  - Advertisements
  - Public relations materials
  - Internet documents
  - Patient education



# Documents in the product lifecycle



# Drug Approval Process



# Qualifications and Skills

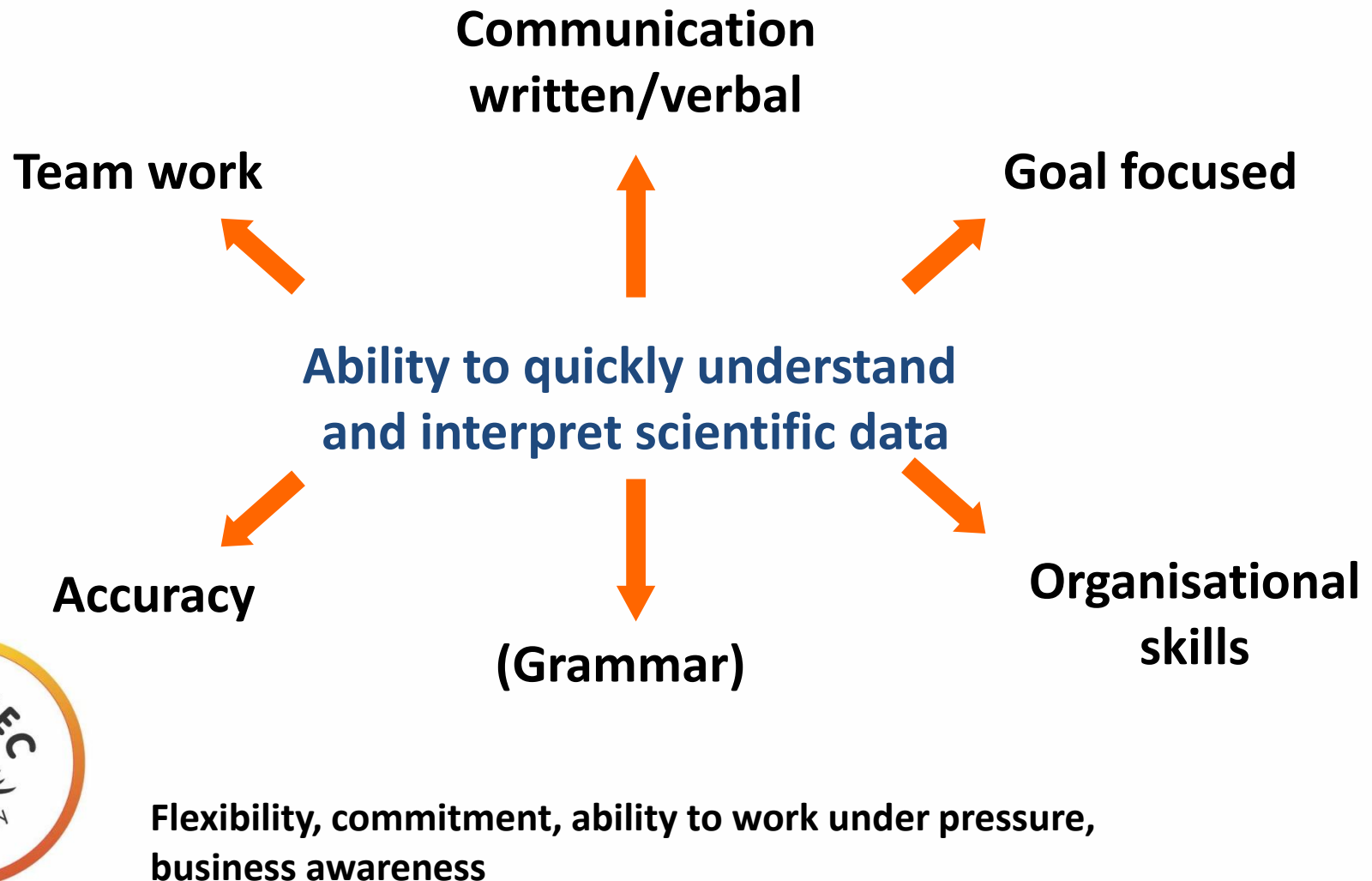
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- Ability to write and enjoy writing!
- Life sciences degree
- Ability to assimilate information quickly
- Enjoy working with huge amounts of data
- Attention to detail
- Work under pressure and meet deadlines
- An understanding of statistics
- Proficiency in Microsoft Word



# Key Attributes To Fulfill The Role

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# How to Get Started?

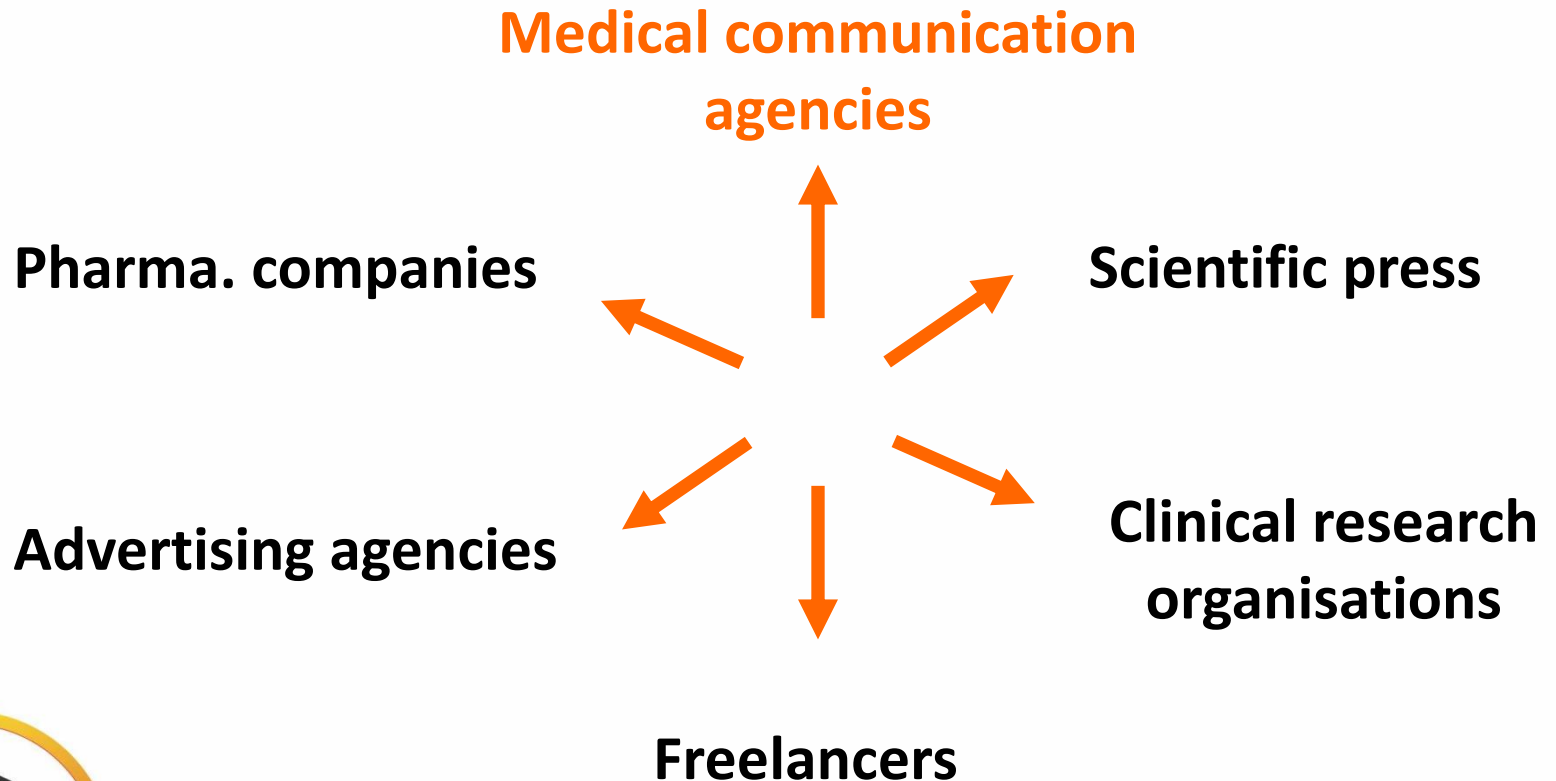
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- Contract Research Organizations/ Companies willing to take on those with aptitude
- Written a thesis
- Published papers
- Be prepared to take a test
- EMWA ( European Medical Writer's Assn)
- Training Positions for Regulatory Staff



# Medical Writers

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# Pharmaceutical companies



## Medical community

### Publications

- Journal articles
- Book chapters
- Abstracts

### Congress activities

- Oral presentations
- Posters
- Booth panels

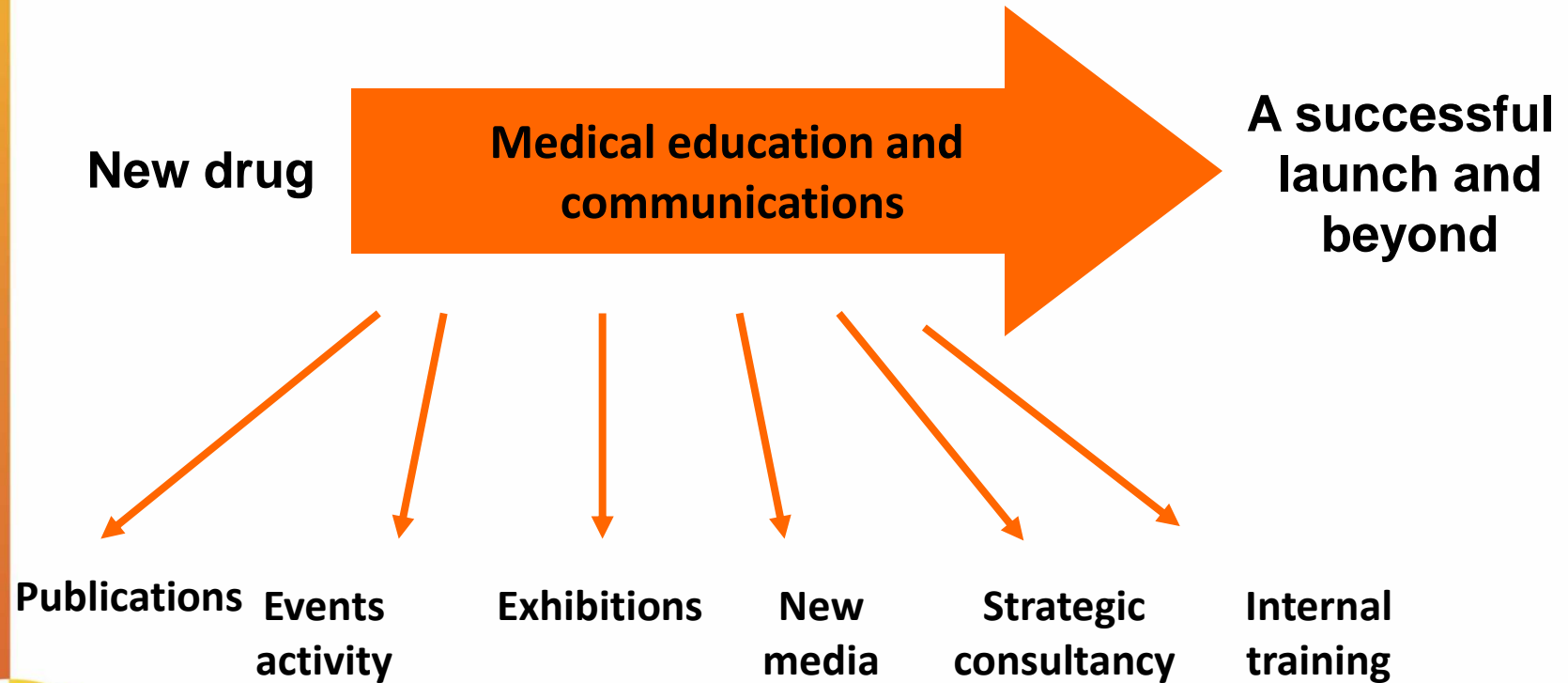
### Training & education

- Physician slide sets
- Sales Rep. training
- Newsletters



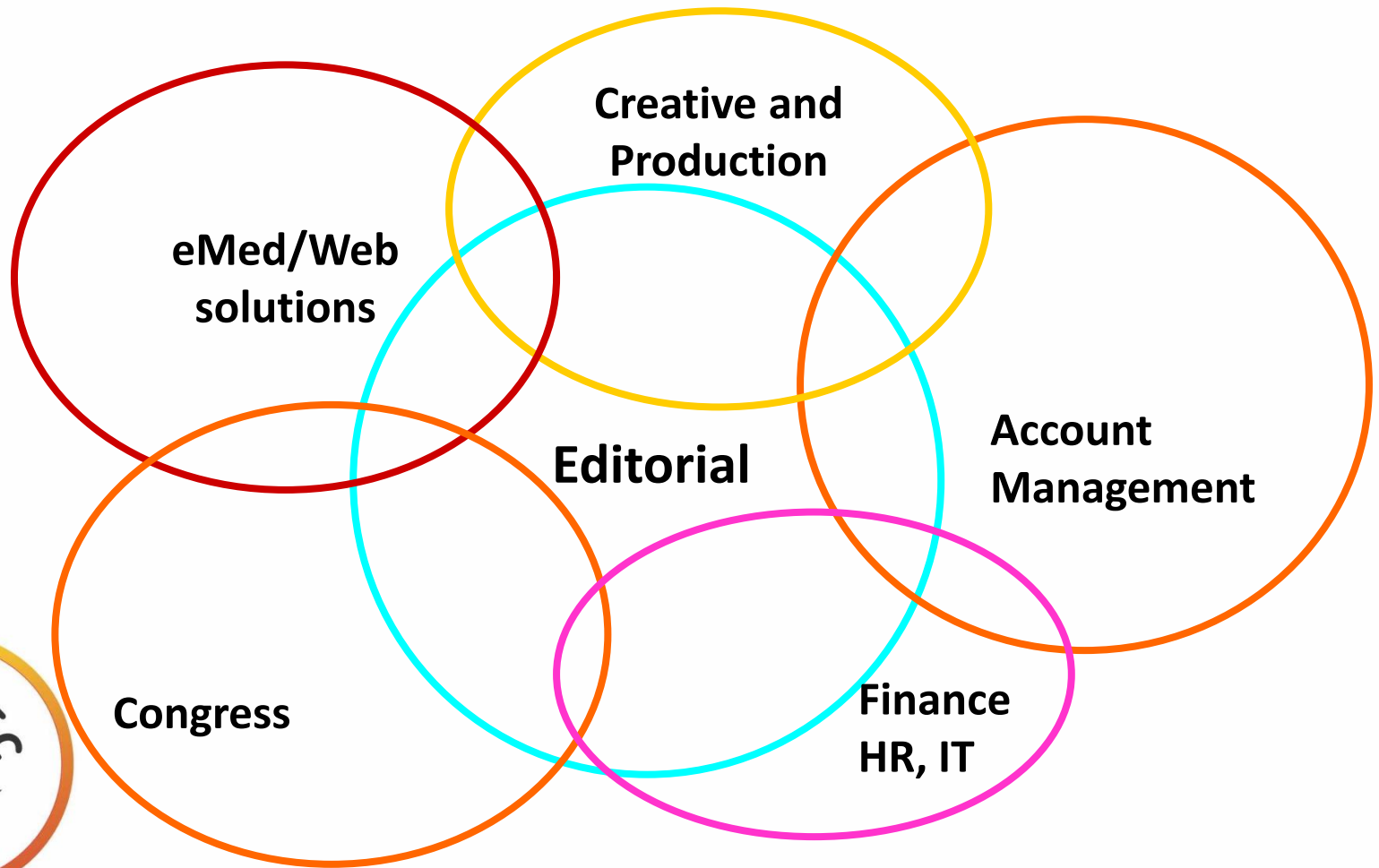
# Product/publication managers clinical scientists

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# Medical Writers - Central To The Team

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# Typical Day...

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- Working with 5 different pharmaceutical companies
- Writing on 8 different drugs:
  - Diabetes, incontinence, fertility, cardiovascular disease...
- Liaise with clients to ensure information about drug is communicated most effectively
- Work with 'author' to ensure we're writing what they want to say
- Liaise with in-house studio to ensure all art-work contains client's branding and colours
- Dealing with 50-100 emails per day



# Career Structure

