

Medical Writing in the HEOR World
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May 5, 2012

Agenda

- Introduction
- What we write
- How we manage what we write

Introduction

- My Background
 - Athletic training to Pharma
 - Research to writing to project management
 - Current role
 - Medical Writer/Project Leader at CRO in Market Access and Value Strategy
- HEOR
 - Health economics and outcomes research
 - Within HEOR at Optum is Market Access and Value Strategy (MAVS)

What We Write

- Manuscripts
 - With researchers from our own HEOR group who do late-phase and retrospective database analysis in conjunction with clients
 - Directly with clients
- Literature Reviews
 - Conduct rigorous reviews and analysis of clinical, economic, health and patient-reported outcomes
 - Inform strategic decisions related to product development and relative value
 - When: Throughout lifecycle (can be used for modeling, dossier development, meta-analyses or publication)
- Meta-Analyses
- Regulatory
 - Late phase
- Dossiers

Dossiers – For Submission (Health Technology Assessments – HTA)

- US
 - AMCP: clinical and economic evaluation to support formulary listings in health plans (guidelines:
[http://www.amcp.org/data/imcp/1007_121%2019%2009\(3\).pdf](http://www.amcp.org/data/imcp/1007_121%2019%2009(3).pdf))
 - Wellpoint (guidelines:
<http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=12532>)
- Outside US
 - UK's NICE (National Institute for Health and Clinical Excellence)
 - Sweden's TLV (Dental and Pharmaceutical Benefits Board)
- Phase of development
 - Close to or at launch; new indication
- Where we get the content
 - Largely from a GVD if one has been developed
 - Client provided information – recent abstracts, product label, lit search
- “Just the Facts”

Dossiers –Value

- Internal documents that may be distributed to affiliates
 - A comprehensive document that integrates burden of the disease, clinical and economic evidence, regulatory and marketing information that supports product value and helps gain full market access
 - The information is to be customized by each Affiliate to effectively communicate the value of product in each market
- Presents the value story to show differentiation of product:
 - Disease Info
 - Unmet need that product will address
 - Clinical evidence – direct comparison if possible
 - Economic evidence – direct comparison if possible

Dossiers –Value (con't)

- Phase of development:
 - can begin pre-clinical/early clinical – usually more disease oriented
 - Updated several times during development
- Where we get the content
 - Systematic literature searches
 - Information provided by client – study reports, investigators brochures, value statements
 - Online sources – disease associations (treatment guidelines), regulatory agencies,
- “Tell a Story”; more creative
- Types
 - Global value dossiers
 - Core reimbursement or disease state dossiers

How We Manage What We Write - Dossiers

- Dossiers are very large, comprehensive documents
 - On average a submission document such as an AMCP dossier can be 100-120 pages
 - Value dossiers are much larger – 200 up to 500 pages including appendices

Value dossiers have several elements to help make them user-friendly and help summarize and call out important information

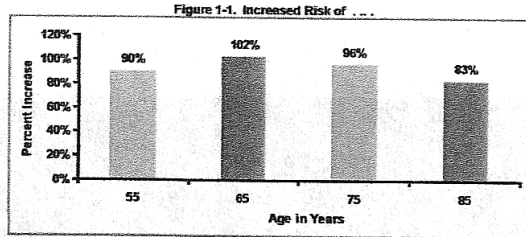
Value dossiers are comprehensive documents that integrate burden of the disease, clinical and economic evidence, regulatory and marketing information that supports product value and helps gain full market access. Different elements are used through the document such as call out boxes, summary tables and figures and tables.

For Affiliates: The global cost-effectiveness model uses ... Smith et al, 2009²⁷.

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Regardless of age, patients with ... have twice the risk of future ... compared with those with no prior ...

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Smith et al²⁷

Section 2. Product information and disease description

2.1 Product description

Vaccine XYZ is a sterile, liquid vaccine consisting of a mixture of purified [...].

Comment [KLO1]: XYZ Company, Vaccine XYZ Product Information, 2010

Vaccine XYZ is a clear, colorless solution. Each 0.8-mL dose of vaccine contains 30 micrograms of ... in isotonic saline solution containing 0.25% phenol as a preservative. The vaccine is used directly as supplied. No dilution or reconstitution is necessary.

2.1.1 Dosage forms, strength, and package sizes

Vaccine XYZ is a sterile, liquid vaccine consisting of a mixture of purified [...].

Comment [KLO2]: XYZ Company, Vaccine XYZ Product Information, 2010

Vaccine XYZ is a clear, colorless solution. Each 0.8-mL dose of vaccine contains 30 micrograms of ... in isotonic saline solution containing 0.25% phenol as a preservative. The vaccine is used directly as supplied. No dilution or reconstitution is necessary. PNEUMOVAX 23 is supplied as follows:

2.1.2 Indications and Usage

2.2 Place of Vaccine in therapy

2.2.1 Approach to vaccination

The World Health Organization (WHO) has issued two recent position papers on XYZ disease vaccine. The most recent was published in April 2012 and

National recommendations for vary greatly from country to country

Comment [KLO3]: WHO, Weekly Epidemiological Record, April 6, 2012, No. 14, 2012, 11, 111-111; <http://www.who.int/wer>

focuses mainly RRR and SSS and their use in children. It replaces a document from 2004 and while it briefly touches on TTT, the 2002 position paper on TTT remains valid. With regard to RRR, WHO recommends their inclusion in childhood immunization programs worldwide and countries with high childhood mortality should make the introduction of RRR a high priority. Other control measures to prevent XYZ disease should still be encouraged and the choice of RRR should depend on such factors as:

Comment [KLO4]: WHO, Weekly Epidemiological Record, April 6, 2012, No. 14, 2012, 11, 111-111; <http://www.who.int/wer> page 111, A5

The position paper issued by WHO in 2008 provides recommendation for the use of PPV23. results have been reported in some high-risk populations. While WHO states that many industrialized countries recommend PPV23 immunization of their elderly and other high-risk groups they state that in "resource-limited settings where there are many competing health priorities, the evidence does not support routine immunization of the elderly and high-risk populations with PPV23". They cite the effects of herd immunity from PCV7 immunization and recommend giving higher priority to introducing and maintaining high coverage of infants with PCV7. With regard to HIV-infected

Comment [KLO5]: Smith et al., Sports Phys Ther, 2011 (page 11, A5)

Comment [KLO6]: WHO, Weekly Epidemiological Record, October 17, 2008, No. 13, 2011, 11, 111-111; <http://www.who.int/wer> page 111 A2 and 3

• GVD's can sometimes take up to a year to complete and can contain hundreds of references
• Annotating helps keep track and is invaluable during the QC process



Thank You.

Contact information

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