INTEGRATING HEOR INTO A SCIENTIFIC AND STRATEGIC COMMUNICATIONS PLATFORM

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PharmaWrite Vision and Philosophy

- Our vision is that everything starts with the science
- Guiding principles to achieve success
  - Strength in scientific content and medical writing
  - **Breadth and depth in regulatory, clinical, and HEOR content**
  - Staff expertise in multiple therapeutic areas
  - Knowledge of best practices in professional medical writing
  - Our extensive knowledge of the healthcare marketplace
  - Depth of experience in developing integrated medical communications programs
  - Attention to detail and dedication to customer service
  - Relationships with clinical, academic, and investigator communities
- Our mission is to improve patient care by providing opportunities for healthcare professionals to share their research, knowledge, and clinical practice skills

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Full-Service Capabilities

Professional Medical Writing

- Primary and secondary manuscripts
- **HEOR-focused manuscripts**
- Clinical study reports
- Scientific reviews
- Supplements
- Case reports, short communications
- Abstracts and posters
- Podium presentations
- Newsletters
- Congress highlights, independent proceedings
- White papers
- In-house communications/ presentations
- Includes coordination of publication team

Strategic Communications

- Scientific communication platform
- Competitive landscape analysis
- Data dissemination plan
- Gap analyses
- Competitive surveillance
- Audience identification
  - Scientific meetings, journals
- Product life cycle development
- Communication plan management
- Core content development
- **Core/Global Value Dossier**
- **AMCP Dossier**
- Slide kits
- Monographs
- Product information materials

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Full-Service Capabilities *(cont)*

Additional Services

- Regulatory writing
- **Managed market strategy and tactics**
- Competitive surveillance/website
- Speakers bureau management
- Decision tree analyses
- Scientific liaison training
- Sales training materials
- Compendium/reference management
- Scientific event planning

Advocacy Development

- Thought leader identification
  - Authorship metrics
  - Presentation metrics
- Advisory boards
- Roundtables
- Investigator meetings
- Clinical trial surveillance
- Speaker training
- Regional consultant meetings

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Experienced Team of Professionals

PharmaWrite establishes full-time, in-house account teams specific to client needs

- **Medical Writers with PhDs in the Life Sciences, PharmDs, and MPHs**
- Scientific Managers with advanced degrees and extensive experience
- Medical Editors with diverse advanced degrees
- Professional Medical Librarians
- Graphic Designers and Presentation Specialists
- Meeting Planners and Meeting Assistants
- Information Technology Specialists
- Website Strategists/Online Content Managers
- Speakers Bureau Program Coordinators

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Extensive Medical Library

- Have employed professional librarians for >13 years
  - 3 full-time librarians with master of library science (MLS/MLIS) degrees
- Medical library with >140,000 references in database
  - 99% success rate for document delivery using our Publisher-Token subscription
  - Subscriptions to Dialog and other electronic databases
  - Electronic copies of every reference used in each manuscript saved in our database
- Proprietary databases of journals and congresses by therapeutic area
  - All publication and congress characteristics
- Subscriptions to Sylogent Conference Authority/Journal Selector and PubsHub supplement our proprietary database
- Access to world's largest (proprietary) medical abstract database
  - Full-text abstracts, monitoring over 7,300 medical meetings worldwide
- Our annual license with Copyright Clearance Center allows us to obtain and share most articles with clients

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Library

Full-service information center

- Literature searches and analytics services

- Access to a large number of relevant medical and scientific databases

- Document delivery

- Congress and journal databases

- Managing database of PDFs and source documents (Reference Manager)

Staffed by 3 full-time professional

medical librarians
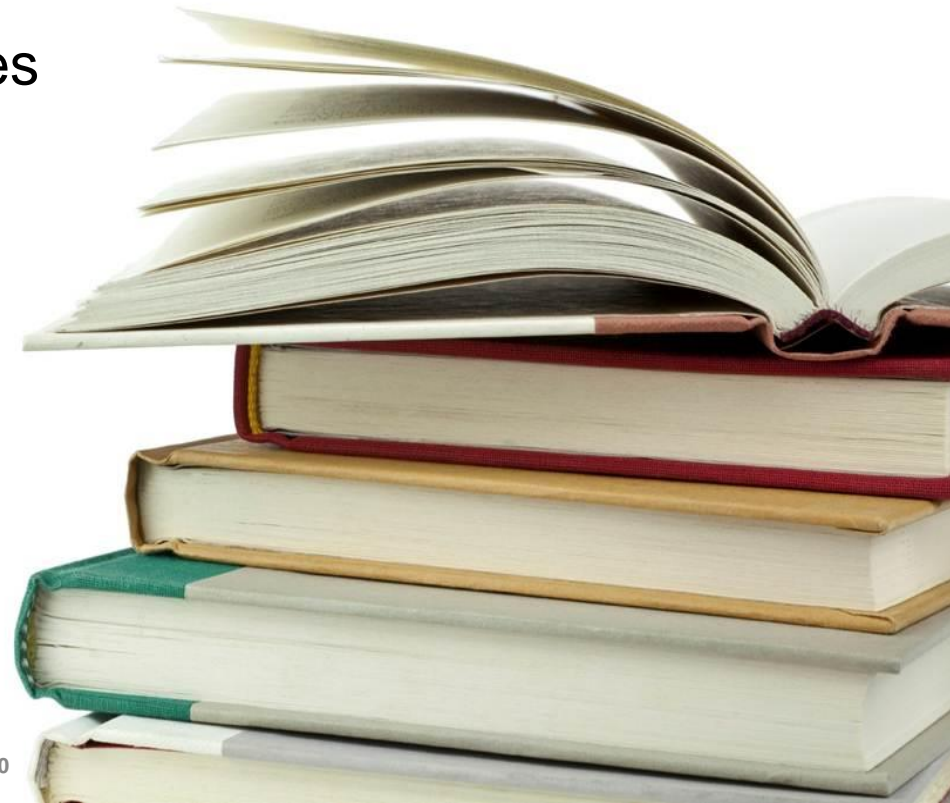
BUILDING A SCIENTIFIC AND STRATEGIC PLATFORM

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Scientific and Strategic Platform Framework

OBJECTIVE: Provide a unified and consistent source of information for the product that can help direct future communication activities

- **Lexicon:** Terms and phrases that describe and differentiate the product

- **Key Scientific and <u>Value Statements</u>:** Referenced sentences provide a platform from which tactics are planned and organized

- **Gap Analysis:** Assessment of the evidence base for current scientific statements, uncovering the "gaps"

- **Situational Analysis:** Summary of challenges and opportunities in the disease space, burden of disease, treatment approach and product, including a SWOT, as grounded in the scientific literature

- **Educational Gap Analysis:** Perceptions from the literature, competitive intelligence, guidelines, and health technology assessment (HTA) organization reviews summarized

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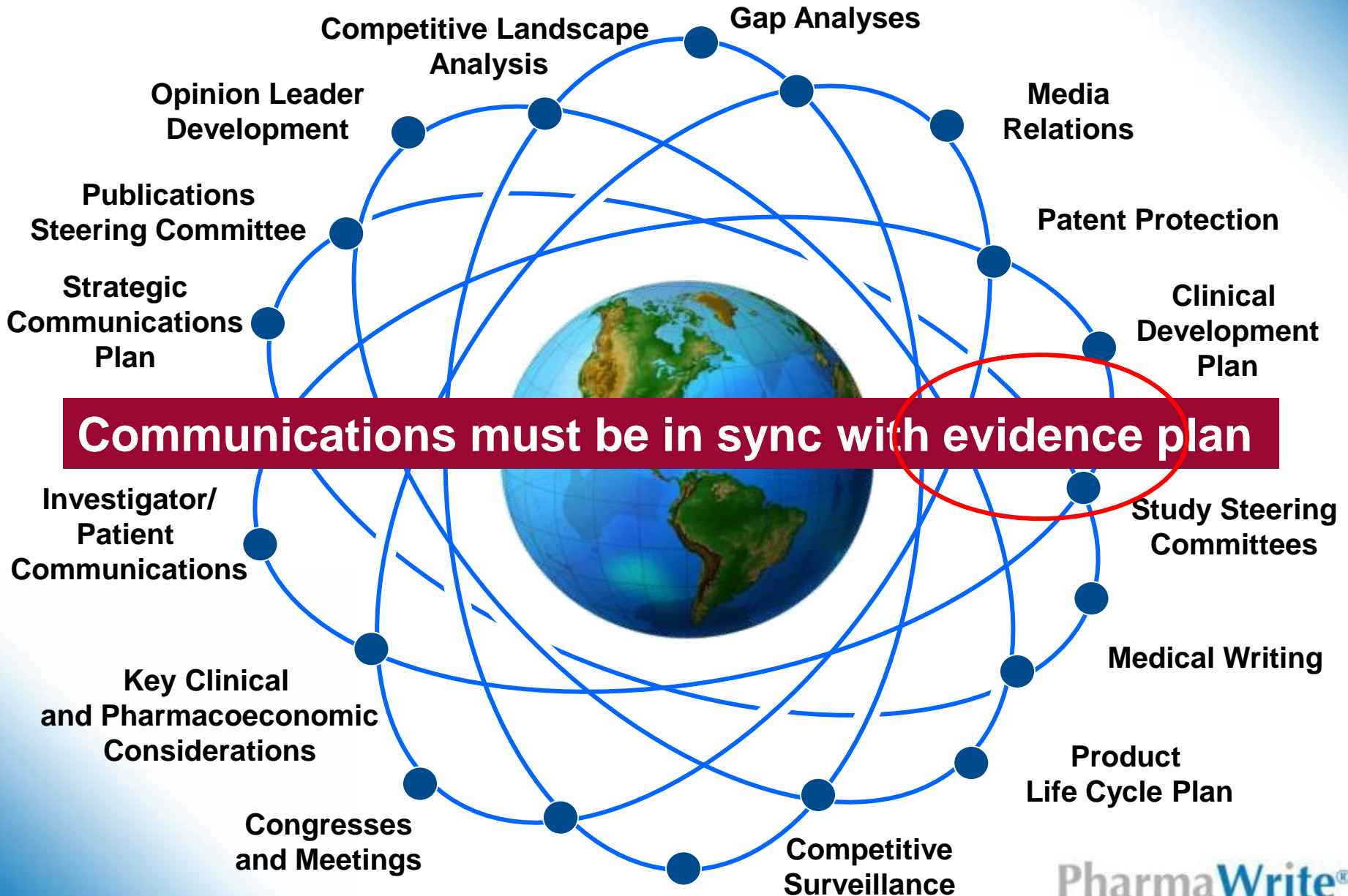
Data and Documents to Be Requested

- Listing of clinical or value messages that are supported by existing data or that will be tested by current or future trials (ie, "aspirational" outcomes or scientific messages)
- Competitive landscape analysis
- SWOT slides
- **Burden of disease and economic modeling information**
- Summary of market research
- Summary grid of completed, ongoing, and planned trials with endpoints, comparators, results, and presentation/publication notes
- List of unpublished data, including preclinical and Phase 1
- Comprehensive list of advisors
- Executive summaries of pivotal and recent advisory board meetings
- CSRs of pivotal and unpublished or incompletely published clinical trials
- Current clinical manuscript drafts
- Poster or podium presentations
- Any other materials [client] would like us to review

If the client does not have all of these items, PharmaWrite can help to create or compile them.

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INTEGRATION OF HEOR TO A SCIENTIFIC COMMUNICATIONS PLAN

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Strategic Overview of Communications Plan

Competitive Landscape Analysis

Gap Analyses

Opinion Leader Development

Media Relations

Publications Steering Committee

Patent Protection

Strategic Communications Plan

Clinical Development Plan

Communications must be in sync with evidence plan

Investigator/ Patient Communications

Study Steering Committees

Key Clinical and Pharmacoeconomic Considerations

Medical Writing

Product Life Cycle Plan

Congresses and Meetings

Competitive Surveillance

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Harmonize Clinical and HEOR Plans

- **Publications Steering Committee**
  - Include reimbursement/HEOR perspectives in larger discussion
  - Clinical and HEOR working teams may be divided
- **Needs Assessment and Gap Analysis**
  - Include gaps on epidemiology, healthcare utilization
  - Burden of disease for patients, caregivers, health systems
- **Tactical Recommendations**
  - HEOR studies may include clinically relevant endpoints
  - Systematic reviews may include discussion of healthcare utilization and costs
- **Operational Efficiencies**
  - HEOR publications may be accelerated when professional medical communication strategies are applied

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HEOR-Specific Considerations

- **Literature foundation**
  - Ensure robust search and context from published work
- **Author support**
  - Provide research experts with editorial and strategic services
  - Offer process efficiencies and publishing best practices
- **Optimize appropriate venues**
  - Help translate work to additional audiences for broader submissions
- **Communicate internally**
  - "Show off" cross-functional collaboration and best practices
- **Consider post-publication integration**
  - Partner with field teams to optimize integration of value story elements, provide timelines, and help manage expectations

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HEALTH ECONOMIC & OUTCOMES RESEARCH COMMUNICATIONS

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Health Care Decision-Making Is Evolving

- **Increasing demand for efficiency and value**

  - Clinical and coverage decisions are more closely connected

  - Coverage and utilization decision-makers are consolidating

  - R&D must anticipate reimbursement requirements

  - Expected or actual <u>effectiveness</u> is evaluated and applied to decisions

  - *Customer-specific information is becoming a requirement*

- **As costs to patients increase, so does patient voice**

  - Consumer-oriented medical information is widespread, mixed

  - Patient education and engagement efforts are growing

  - Rare diseases and specialty treatments garnering more attention

  - Product research needs to consider patient perspective

  - *Advocacy groups are decision stakeholders*

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Changing the Engagement Model with Evidence

With demands for higher quality and more efficient care, stakeholders are turning to a value-based structure

Cost Containment Measures

Focus on Pharmacy Budget

- Increasing member contributions
- Access restrictions
- Discount/rebate orientation

Utilization Restrictions

- Rigid formularies
- Prescribing guidelines
- Generic prescribing
- Reimbursement restrictions

Value-Based Decision-Making

Best Practices & Quality of Care

- The right treatment at the right time
- Risk stratification
- Pay for performance

Appropriate Utilization

- Population management programs
- Evidence-based formularies
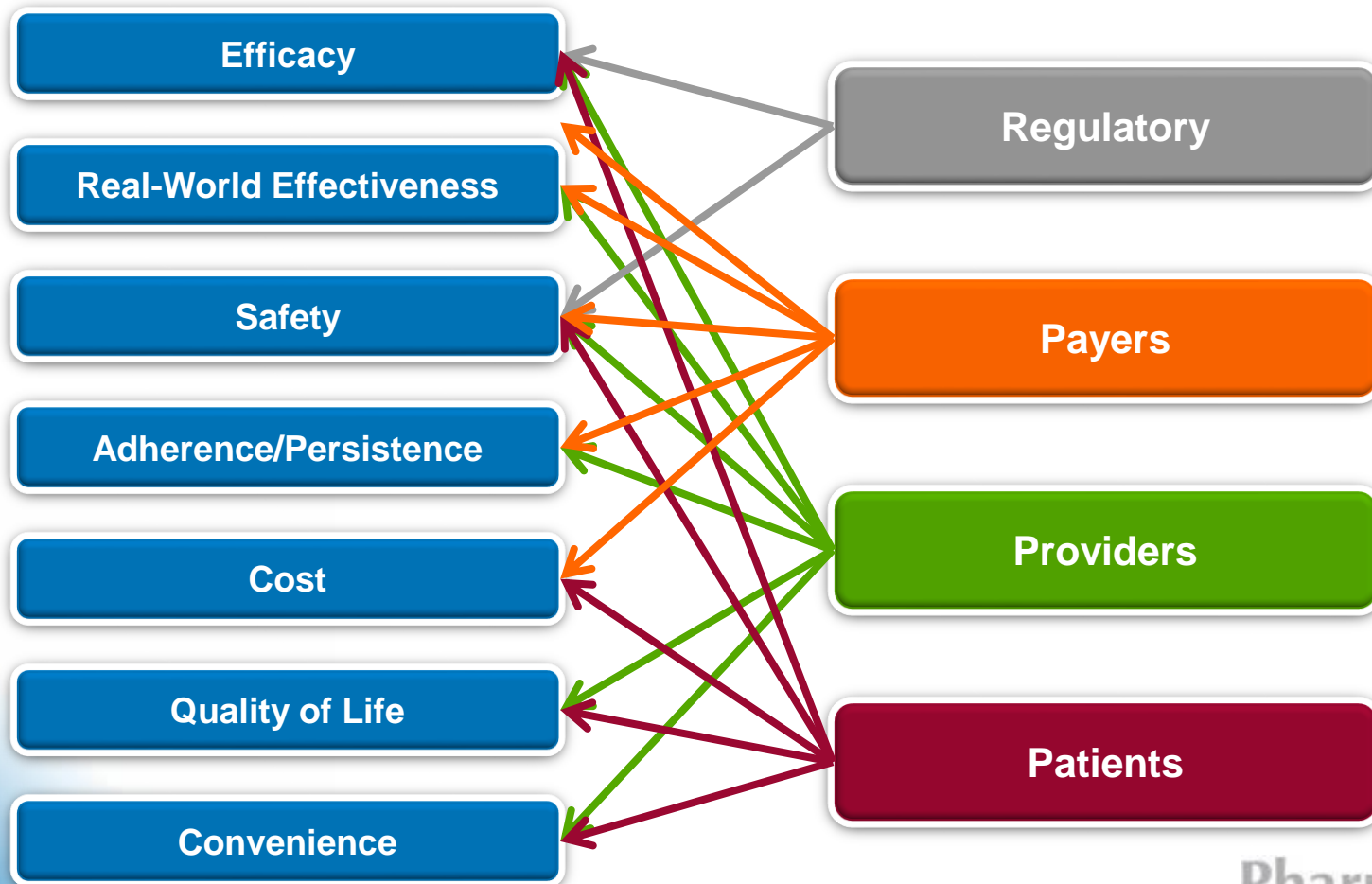- Cost offsets, total cost of care

What is the evidence of "real world" effectiveness?
How is that evidence best applied to decisions?
How does that evidence translate to patient care?

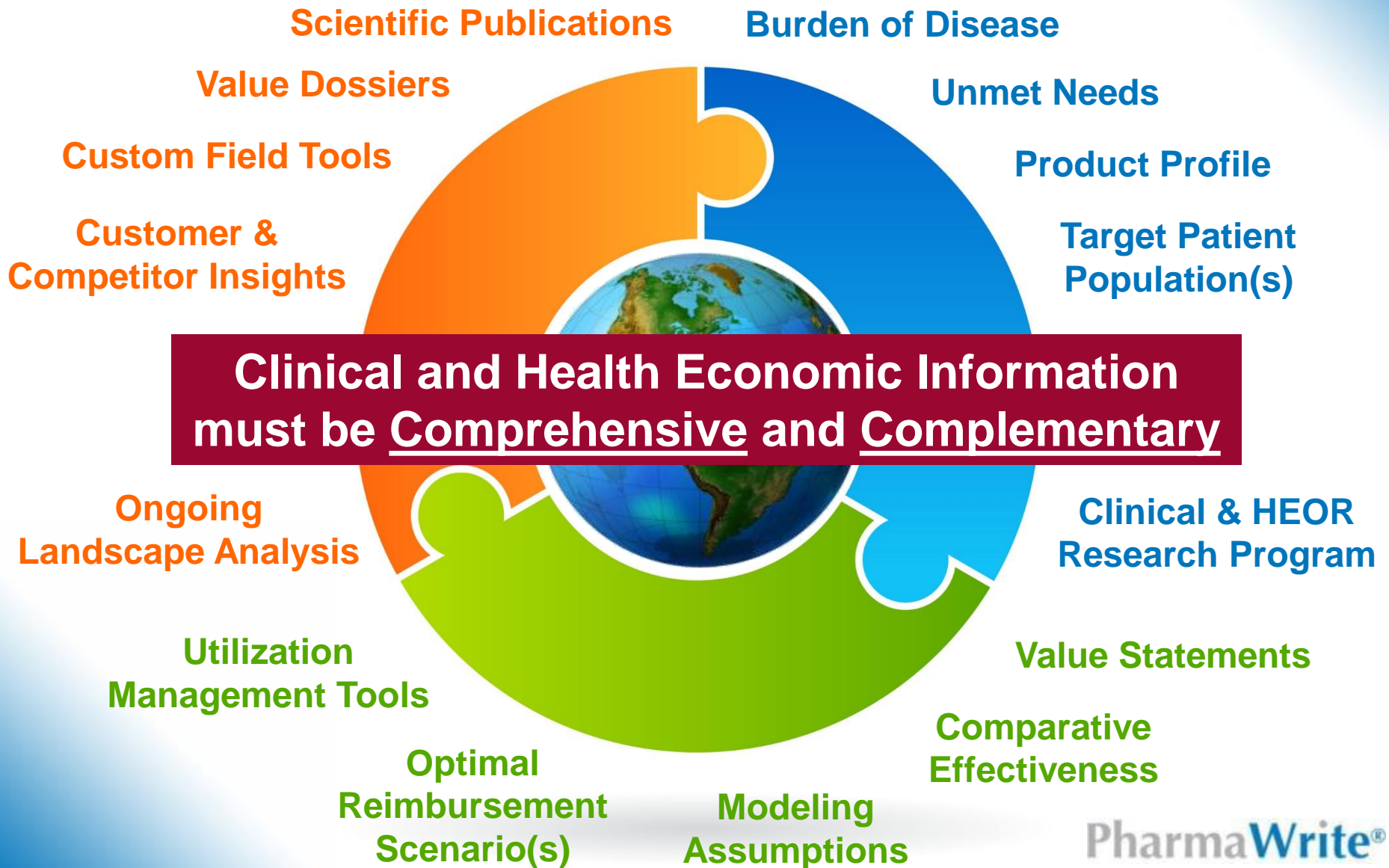PharmaWrite®

Characterizing Value

- **Patient population and the burden of illness**

- **Unmet needs** in disease management

- **Value proposition** of emerging treatment option(s)

  – Product attributes and clinical research program

  – Differentiating clinical, humanistic, and economic benefits

  – Sub-population benefit-risk considerations

  – Stakeholder-relevant effectiveness research

- **Appropriate utilization, point-of-care decision support**

  – Translation of evidence into practice

  – Disease management, compliance/adherence programs

  – Stakeholder-focused implementation tools

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Value Communications Must Be Aligned

Scientific Publications

Value Dossiers

Custom Field Tools

Customer & Competitor Insights

Burden of Disease

Unmet Needs

Product Profile

Target Patient Population(s)

Clinical and Health Economic Information must be Comprehensive and Complementary

Ongoing Landscape Analysis

Clinical & HEOR Research Program

Utilization Management Tools

Value Statements

Comparative Effectiveness

Optimal Reimbursement Scenario(s)

Modeling Assumptions

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PharmaWrite HEOR Services

We bring professional medical communication expertise to HEOR and other value-based initiatives

Development & Market Evaluation	Pre-Launch	Launch	Competition

Development & Preparation

✓ Understand evidence landscape

✓ Characterize unmet needs

✓ Evaluate care challenges & treatment options

✓ Assemble evidence supporting value story

✓ Develop & update product dossiers, field materials

Differentiation & Support

✓ Evidence supporting for disease burden and financial impact models

✓ Literature context for HEOR study presentations

✓ Develop systematic reviews on key topics

✓ Apply professional best practices to HEOR publication plans

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PharmaWrite Is a Full-Service Partner

Professional Library Services

HEOR Writing Expertise

Professional Medical Communications

HARMONIZED VALUE COMMUNICATIONS

- ✓ Comprehensive Landscape Assessments
- ✓ Burden of Illness Literature Review
- ✓ HEOR Study Publications
- ✓ Integrated Field Presentations
- ✓ Value Dossiers
- ✓ HEOR Medical Information Letters
- ✓ Operational Efficiencies
- ✓ Unified Policy Compliance

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