

## Background

Each pharmaceutical company is responsible for the development of clinical data which ultimately leads to product approval. Data from clinical trials are used by local Medical Information groups to develop standard response documents to respond to healthcare professionals and consumers. The current approach is for each country or regional area to develop response documents for their own use.

## Objective

To assess the functionality of global medical information in various pharmaceutical companies with a focus on the development of standard responses and their availability to internal stakeholders worldwide.

## Methodology

## Design

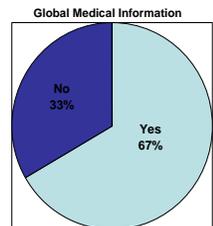
A twenty-nine question web based survey was distributed electronically via SurveyMonkey.com<sup>®</sup> to twenty-two different pharmaceutical companies. The survey was structured to assess the process, location, and dynamics of the global medical information function at various pharmaceutical companies. Approximately 1/2 of the survey questions were structured to obtain information regarding the central repository or database that contains the global medical information documents and the development, review, approval, and maintenance of the system. The remaining survey questions dealt with the global medical information function and location, formal structure and standard operating procedures (SOPs), and metrics. Of the 29 questions, 28 were multiple choice. However due to the nature and context of the multiple choice questions, 8 were "check all that apply" and 18 were either open-ended or provided room for additional comments. Participants were allotted four weeks to complete the survey. All responses were kept anonymous.

## Evaluation of Respondents

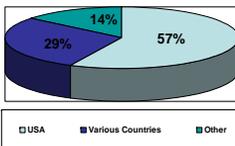
- Of the 26 key representatives contacted, 35% completed the survey (N=9).
- 66.7% (n=6) of the survey respondents have a global medical information function.
- 33.3% (n=3) of the survey respondents do not have a global medical information function.
  - 22.2% (n=2) of the survey respondents did not complete the survey.
  - 11.1% (n=1) of the survey respondents stated that they did not have a formal department but there is cooperation between the groups.

## Results

### Global Medical Information Function



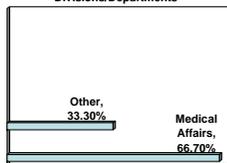
Location of Global Medical Information



- 71.4% GMI function is not located at the company HQs

### Formal Structure/SOPs

Global Medical Information Divisions/Departments



- 66.7% GMI is located within the Medical Affairs department
- 50% have a 7-10 full-time employee staff
- 85.7% have SOPs

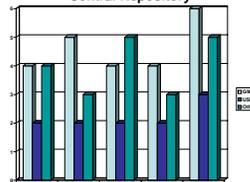
### Central Repository/Database

Storage of Global Documents in a Central Repository



- Of those using a central repository:
  - 57.1% use a document management system
  - 42.9% use a intranet based system

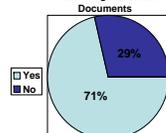
Departments Responsible for Global Documents within Central Repository



- 71.4% of the global documents are in generic format
- 71.4% of the companies surveyed have an official review process for global documents
- 85.7% of the global documents are in English
- 71.4% do not have quality control measures to assess accuracy of translation

### Metrics

Track Usage of Global Documents



- Of those who track usage of global documents:
  - 80% are tracked by GMI
  - 50% perform metrics quarterly

## Discussion

- Majority of respondents (67%) have a global medical information function.
- It is primarily located within the Medical Affairs department.
- 86% of the companies store their global medical information documents in a central repository.
- The majority of companies surveyed rely on GMI to develop, control, review, approve, and maintain the central repository.
- The global documents are in a generic form so that each country can format according to their respective labels.
- The global documents are in English and then translated into the language of the respective country.
  - A majority (71.4%) of the companies do not have quality control measures in place to assess the accuracy of the translation.
- The global response documents are tracked by GMI and metrics are performed quarterly.
- Thus, allowing pharmaceutical companies to provide a consistent message along with possible cost-savings. This may also decrease regulatory and compliance issues.

## Limitations

- The small sample size (N=9) makes it difficult to generalize the findings.
  - Only descriptive statistics were used to analyze the data.
- Survey questions were not validated.
- Respondents may have been from pharmaceutical companies of various sizes and global reach.
  - Organization size and global reach may influence whether or not the company has a formal global medical information function.

## Conclusions

- Standard response documents are an important part of how pharmaceutical companies communicate with consumers and healthcare providers. It is important that companies develop generic response documents that can be used globally.
- Additionally, these findings demonstrate the need for a central repository to contain the global standard response documents.
- It is important that there is an official review process in place for the inclusion of the global documents in the central repository.
- Overall, the findings from this survey assess the current status of global medical information documents and provide insight into the potential expansion and structure of the GMI function at various pharmaceutical companies. However, further investigation and a larger sample size is needed to adequately determine its importance and value.

## References

- Werner AL, Poe TE, Graham JA. Expanding Medical Communications Services to Internal Customers. *Drug Information Journal*. 2000; 34:1053-1061.