CALIFORNIA STATE UNIVERSITY SAN MARCOS

PROJECT SIGNATURE PAGE

PROJECT SUBMITTED IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE

MASTER OF SCIENCE

IN

BIOTECHNOLOGY

PROJECT TITLE: Evaluating Communication Channels and Practices Within and Across the Ardea Phase 3 Clinical Program

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THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN PARTIAL FULLFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE

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EXECUTIVE SUMMARY

Evaluating Communication Channels and Practices Within and Across the Ardea Phase 3 Clinical Program

Ardea Biosciences, Inc., a wholly owned subsidiary of AstraZeneca, PLC.

May 14, 2013

Professional Masters Degree Program

California State University San Marcos

Ardea Biosciences, Inc., a wholly owned subsidiary of AstraZeneca, PLC., recently developed several gout drugs, with Lesinurad as the most advanced product candidate in Phase 3 clinical trials. A new organizational structure was implemented for executing the late phase clinical studies. In hopes of successful Federal Drug Administration approval of this new product, the new structure follows a chartering-based system, constructed to manage individual studies by cross-functional teams, assigning individuals to specific studies as their main focus. As the clinical program moves forward, communication efficiency becomes a key aspect in ensuring project consistency within and across the organization. The purpose of this Semester-In-Residency (SIR) project was to identify the information requirements needed by each functional group within and across study management team (SMT) members, along with additional layers of management. Using a qualitative approach, an initial survey questionnaire examined the clinical program’s organization at the core and extended level, identifying information requirements and barriers that prevent proper information sharing. The survey was administered to 30 people, and the results assisted in defining a standard process for project information sharing that is more efficient and effective for the organization. As a result, the survey responses were used to help design Project Central, a Microsoft SharePoint server, which was implemented as a seamless communication portal for all project information. An introduction of this platform was presented to all study management teams before its initial launch to the entire company. Project Central was developed as the technical solution for all current and future clinical projects, allowing all functional groups to access the information they need to successfully perform their jobs and bring about the desired outcome to the Phase 3 clinical projects.
Evaluating Communication Channels and Practices Within and Across the Ardea Phase 3 Clinical Program

By: Kathy Truong
### Ardea Biosciences, Inc.

<table>
<thead>
<tr>
<th><strong>Lesinurad</strong></th>
<th><strong>AstraZeneca, PLC.</strong></th>
<th><strong>Phase 3 Clinical Trials</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Discovered in late 2007</td>
<td>• A global biopharmaceutical company</td>
<td>• Eight clinical studies</td>
</tr>
<tr>
<td>• Treatment drug for gout patients</td>
<td>• Acquired Ardea in June 2012</td>
<td></td>
</tr>
</tbody>
</table>

**If you or your family has been coping with GOUT, now is the time to act!**

Lowering your serum uric acid may help decrease attacks. Over-the-counter medicine for pain and swelling may not be able to control your serum uric acid level. If your uric acid levels are not controlled, your gout attacks can become more frequent and more painful.

*Join a research study and receive study-related medical care for your gout.*

*To find out more, visit [www.joinstudy.com](http://www.joinstudy.com).*

*For study and patient information call 1-888-286-JOIN (5646).*

*Study is sponsored by AstraZeneca. Participation voluntary and personal information kept confidential.*
**Background:** A new organizational structure was recently implemented for the Phase 3 clinical program.

**Late Stage Group**
- Clinical Development
- Clinical Operations
- Biostatistics
- Project Management
- Data Management
- Clinical Trial Materials
- Regulatory Affairs
- Medical Writing
- Safety
- Quality Assurance
Each study management team is comprised of core functional groups and extended functional groups.
The purpose of this SIR project was to identify the information requirements for each functional group and SMT.

**Challenges**
- Managing communication flow in each SMT
- Implementing a standard process for project information sharing

**Importance of Project**

Effective Teamwork + Communication Efficiency + Project Information Sharing = Success in Phase 3 Clinical Program
Methodology

1. Observe SMT meetings
2. Generate survey questions
3. Pre-test questionnaire
4. Distribute surveys to all SMT members
5. Collect survey responses
6. Analyze survey responses
7. Incorporate information contents into Project Central
8. Conduct follow-up survey
9. Present Project Central at SMT meetings
10. Revisit & observe SMT meetings
11. Design Project Central presentation

Flowchart:
- Observe SMT meetings -> Generate survey questions -> Pre-test questionnaire -> Distribute surveys to all SMT members
- Collect survey responses -> Analyze survey responses
- Incorporate information contents into Project Central
- Conduct follow-up survey
- Present Project Central at SMT meetings
- Revisit & observe SMT meetings
Information collected while observing weekly SMT meetings

♦ Meeting process
  – Participation and interaction
  – Decision-making or problem-solving methods

♦ Communication
  – Identified resources used (e.g. meeting agenda, meeting minutes, trackers)
An initial survey was created to identify the information required by functional groups.

- **Questionnaire type**
  - Qualitative
  - Open-ended
  - Knowledge & information gathering

- **Prior to distribution**
  - Pre-tested by three SMT members
Adobe Acrobat tracking was able to produce response rate.

**Challenge**
- Slow response rate

**Resolution**
- Required joint SMT meeting
Results: The survey responses were generalized into project information required from each core functional group.
Results: The survey responses were generalized into project information required from each extended functional group.

Safety
- SAE/ AE Reporting Information
- Processes
- Product Safety Information and Updates
- SUSARs needing submission to IRB

Regulatory Affairs
- Timeline for country submissions/approvals
- Country Regulations
- Timing of IB and yearly updates
- NDA Submission Timelines
- Application Numbers

Clinical Trial Materials
- Changes to supply availability and packaging
- Operational Processes
- Drug Expiration Dates for Trials
- Budgeting Information
- Timelines for supply availability, shipping, etc.
- CTM Reconciliation Information

Quality Assurance
- Input on Study Conduct Trends and Issues Identified
- Site Audit/Inspection Information
Results: Contents required from all functional groups were categorized to select features for the Project Central design.
Results: Each SMT page has a Document Library, Action Item List, and Project News feed.
**Results:** Project Central was introduced to SMT members using the assertion-evidence type method of visual communication.

Project Central will serve as an information tool both within Ardea and across the Ardea-AstraZeneca organizations.
Outcome of SIR Project:

Project Central
Future Directions

♦ Conduct follow-up survey
  – Assess team members’ opinions of Project Central

♦ Revisit SMT meetings
  – Identify improved communication practices
Acknowledgements

♦ Danielle Goodlett
♦ Heidi Princevalle
♦ Terri Metzger
♦ Dr. Betsy Read
♦ Project Management Group
♦ SMT Members
Questions?