The logo of Janus was chosen for the AAPS Drug Candidate Selection Focus Group because Janus is the Roman god of beginnings and passages, which has a direct analogy to the process of a drug being designed, selected and developed. The symbolism of the two heads suggests one head with eyes looking back into Drug Discovery and the other head with eyes looking toward Drug Development and drug commercialization. Invocation of a blessing from Janus is meant to secure good fortune for initial choices and beginnings, such as the initial choice of a drug in the candidate selection process.

Janus – two headed Roman god (symbolizing progression/change from past to future)

- Meg Landis (Pfizer)

The DCS-FG has been very active and productive this past year where we submitted programming idea for symposia, roundtables, Hot Topics, and Open Forum. We have also strengthened our relationship with other focus groups (FG) including Discovery Modeling & Simulation FG, Lipid Based Drug Delivery FG, Excipients FG, and the DDDI Biotechnology Section.

Accomplishments
The article for the DDDI Section on “How are drug development candidates selected?” published in the July 2014 issue of the AAPS News Magazine.

The DCS-FG sponsored roundtable session “Have the strategies for drug candidate selection by developability assessment of pharmaceutical and drug metabolism and pharmacokinetics (DMPK) properties lived up to their expectations?” at the 2014 annual meeting in San Diego was attended by approximately 200 people. This session successfully elicited a lively and rigorous discussion on strategies employed across many different companies and the discovery scientists’ experiences, both positive and negative, with development candidate selection.

In the fall of 2014, the DCS-FG initiated the AAPS/ACS Webinar Series on Drug Design and Delivery led by John Morrison. This is the first time that AAPS and ACS have co-hosted a webinar series. More than 3000 people signed up for the first webinar on Designing Better Drug Candidates by Dr. Paul Lesson.

**Current and Future Goals**

A review highlighting the benefits and examples of early drug discovery support and the challenges we face from the collected industrial view and experiences of a few of our focus group steering committee members is in early draft form and is expected to be completed by the end of this year.

Springer publishing company has accepted our proposal for a book titled “Translating Molecules into Medicines: Cross-Functional Integration at the Drug Discovery-Development Interface” as part of the AAPS Advances in Pharmaceutical Sciences book series. This book will be edited by Shobha Bhattachar, John Morrison, Daniel Mudra and David Bender, and will have contributing authors from various companies. The target publication date is Sept-Oct 2016.

We have also expanded the objectives of the DCSFG to include candidate selection based on therapeutic targets and translation from discovery to drug product development. For example, we will evaluate the critical experiments and data need to deliver a clinical drug candidate that are crucial for decreasing cost and cycle time of oncology drug discovery.

**Steering Committee**

The DCSFG steering committee is made up of a diverse and enthusiastic scientists which includes representatives from over 10 different companies and academic institutions: Annette Bak, Merck & Co., Inc.; Shobha Bhattachar, Eli Lilly and Company; Chris Breen, Novartis Pharmaceuticals Corporation; Suniket Fulzele, CIMA Labs Inc.; Sudhakar Garad, Cubist; Swati Gupta, Allergan; Yu-Hua Hui, Eli Lilly and Company, Grace Ilevbare, Merck & Co., Inc.; Graham Johnson, NuPharmAdvise; Meg Landis, Pfizer Inc.; Marianne Langston, Takeda; John Morrison (Vice Chair), Bristol-Myers Squibb; Darren Reid, Amgen; Dhaval Shah, FDA; Rob Saklatvala, Merck & Co., Inc.; Csani Varga, Blueprint Medicines; and Mehran Yazdanian (Chair), Teva Branded Pharmaceutical Products R&D Inc.

Join our focus group on LinkedIn at [www.linkedin.com/groups?home=&gid=7455846&trk=anet_ug_hm](http://www.linkedin.com/groups?home=&gid=7455846&trk=anet_ug_hm)

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**Dialogue with a Biologist**

*Swati Gupta (Allergan)*

The identification of novel bio-therapeutics is a long and complex process that involves cross-functional disciplines and techniques. This process can be divided into two distinct phases – a Discovery phase and a Development phase.

As members of Drug Candidate Selection Focus group (DCS-FG), we sat with two Biologists to talk about drug developability in general. Here is the summary of those sessions to narrow down the selection in order to minimize the risk and maximize the benefit in assessing the developability of a drug candidate.
1. When we say developability assessment, what comes to your mind as a Biologist?

<table>
<thead>
<tr>
<th>Acceptable Functional Pharmacology</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Qualified Target</td>
</tr>
<tr>
<td>• High affinity in-vitro binding with great potency</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acceptable Physicochemical Properties</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Stability</td>
</tr>
<tr>
<td>• Solubility</td>
</tr>
<tr>
<td>• No modification that leads to aggregation</td>
</tr>
<tr>
<td>• Acceptable isoelectric point</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acceptable Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Works effectively at a safe dose</td>
</tr>
<tr>
<td>• Acceptable PK (exposure, half-life)</td>
</tr>
<tr>
<td>• Great PK/PD relationship</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Acceptable Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Low</td>
</tr>
<tr>
<td>• Immunogenicity</td>
</tr>
<tr>
<td>• Less Adverse events in patients</td>
</tr>
</tbody>
</table>

2. At what stage do you start thinking about fixing the physicochemical and biological properties of the molecule?

Physicochemical and biological properties need to be checked early on during the process of selection. Identifying a protein or class of proteins that is a qualified target and show required biological activity with required stability and solubility is a necessary first step toward an eventual clinical candidate. In Biologics, however there are always few back-up variants that will need to be prepared and tested before a suitable candidate is selected for in vivo assessment. The various characteristics of proteins, such as low potency, limited solubility, poor selectivity across different species, modifications that leads to aggregation and higher chances of immunogenicity are some of the criteria that are limiting criteria during selection process. Re-engineering of the candidate and/or an adjustment in the formulation is necessary to improve the characteristics of lead molecule which is often a major aspect of a drug discovery program.

3. In the early stages of a program, do you think that there are any in-silico prediction tools for pharmacokinetic (PK) and safety that are useful in guiding you through the selection process? Is in vitro assessment any helpful in Biologics? At which stage PK modeling can help?

While advances are constantly being made to improve the predictive tools for PK and safety, they are not a substitute for in vivo studies for Biologics. The common considerations for the ADME for bio-therapeutics include target mediated clearance, the FcRn recycling for Fc containing proteins, immunogenicity, isoform heterogeneity and metabolic stability for small molecular weight proteins and peptides. Many of these challenges for mechanistic ADME studies cannot be answered by in vitro systems. The PK properties are an important attribute which must be suitable for the desired physiological response and must be evaluated before a candidate can move into the realm of in vivo efficacy testing. A mechanistic PK/Pharmacodynamics (PD) modeling can be done using an interdependent PK, biomarkers and efficacy which can be a critical tool to design clinical dose regimens.

Additionally in vitro screening systems can provide an opportunity for the sustained release programs to predict performance/duration in an in vivo setting. Although, immunogenicity in-silico-prediction tools can be useful in helping to select molecules, in-vitro prediction tools are most commonly used to assess immunogenicity using hu PBMC assay. In the absence of suitable PK properties, a lead molecule cannot progress beyond the in vitro stage of discovery.

4. How do you prioritize the following: efficacy, PK, safety, physicochemical and biological properties? Will this be stage dependent?

Each of the properties mentioned above are interdependent and is a part of the optimization process and can get emphasis depending on the stage of the project. For the purposes of designing biological molecule the first thing that comes to mind are safety and efficacy. The PK and physicochemical/biological properties need to be acceptable to provide clinical evidence of effectiveness. Safety is a major factor in determining whether or not the molecule can be used in a clinical setting and is tested during all the three Phases based on the risk of the molecule. To assess safety for Biologics there are no substitute and in vivo assessment is required.
In most cases, it is necessary to determine the NOAEL (No observed Adverse Effect Level) and MABEL (Minimum anticipated Biological Effect Level) of the molecule in order to assess the right dose and relative risk of moving forward. Identifying potential problems as early as possible can significantly decrease program costs and increase overall efficiency in the drug discovery process. Apart from safety and efficacy, numerous other parameters such as formulation, dosing regimen, storage conditions, and the process to fulfill the supply chain, must be addressed before an Investigational New Drug application can be submitted. Once a clinical plan is approved, human trials are initiated. Phase I trials generally focus on safety using healthy volunteers. Then a small set of patients are studied in phase II trials, to determine if the molecule has efficacy and safety in a small controlled patient population and to set the doses that will be used in pivotal phase III trials. Regulatory approval for marketing may be granted if the molecule meets the desired endpoints and safety in the phase III trials. Based on the risk of the molecule, post-marketing surveillance, (phase IV trials) may be required to ensure patient safety and drug efficacy.

**Tech-corner**

**Therapeutic Focused Drug Candidate Selection Criteria: Considerations for the Oncology Drug Candidate**

-Yu-hua Hui, Eli Lilly and Company

The path from target selection to identifying a clinical candidate is long and complicated. The importance of improving R&D efficiency in the pharmaceutical industry has been realized. Numerous publications discussed the complexity of drug discovery and ways to improve the efficiency of the process (1-4). Drug discovery programs have a well-established toolbox of *in silico*, *in vitro* and *in vivo* biological assays by which chemicals are selected and advanced as potential drug candidates. Candidate selection (CS) is considered a major milestone and the recognized point of departure from drug “discovery” into “development” and the selection criteria for a drug candidate have been the topic of frequent discussion in recent years (5-7). Before the initiation of human studies, a drug candidate is expected to satisfy specific and demanding criteria including preclinical safety, efficacy, pharmacokinetic, and physicochemical characterization thought to be consistent with successful human clinical properties. A drug must bind selectively to the receptor site on the target and elicit a desired functional response from the target. It must be “druggable” (able to be formulated to have sufficient bioavailability and appropriate distribution within the body to reach the receptor site), and it must elicit the desired responses *in vivo*, using animal models of the human disease. Most importantly, a drug candidate suitable for testing in humans must pass formal toxicity evaluation in animals, to demonstrate that humans participating in the clinical studies are exposed to minimal risks.

Candidate selection criteria may differ based on the intended therapeutic indication. The assessment benefit: risk ratio may also differ as a function of indication or disease area. For example, with life-threatening diseases (oncology) or other major debilitating conditions (Alzheimer’s disease), the unmet need offers large potential benefit, whereas with drugs for other diseases such as obesity, depression and osteoporosis the risk to benefit ratio is usually different. For diseases where the target is located in the brain, central nervous system penetration becomes a necessity whereas that is not a consideration for a drug candidate acting on a peripheral target. In the end, choosing a drug candidate requires a proper balance of efficacy, ADME (absorption, distribution, metabolism, and excretion) properties, druggability and safety.

A review by Hoelder et al. (8) discussed in depth the four keys steps of oncology drug discovery: 1) target validation and selection, 2) chemical hit and lead generation, 3) lead optimization to identify a clinical drug candidate and finally 4) hypothesis-driven, biomarker-led clinical trials. In this review many special characteristics specifically related to oncology drug discovery are delineated. Oncology targets including kinases, metabolite targets, and many other mechanisms often predispose the chemistry to challenging physical-chemical spaces (9). Other considerations include drug disposition specifically related to the tumor microenvironment and unique toxicology related to their pharmacology. New concepts and technologies have also led to the discovery and development of different types of oncology drugs in addition to small molecules, notably monoclonal antibodies (mAB), fusion proteins, peptides, antibody-drug conjugates (ADCs), vaccines, and oligonucleotides.
Diverse therapeutic approaches to different targets will be essential for treating diverse types of cancers. Another difference is that oncology FHD (first human dose) studies, in most cases, enroll cancer patients instead of healthy volunteers. Thus, the regulatory requirement for oncology drugs and the ethical considerations at FHD might be different from other therapeutic areas e.g. the starting dose should not be too low and should benefit patient’s condition. Defined best practices and desired product profile are essential for successful translation of early discovery results into interpretable clinical outcomes. In addition to the regular CS criteria used for all therapeutic areas, a few more considerations are presented below for a clinical candidate in oncology.

It is now accepted that oncology clinical trials for targeted agents should be enabled by biomarkers. Candidates need to be studied thoroughly to have validated, robust and translatable biomarkers for proper patient selection and combination therapy potential. Because plasma biomarkers don’t require a biopsy in clinic, they typically offer improved translatability from preclinical studies to clinical trials compared with biopsied tumor biomarkers. Of course, target engagement and its relationship to a biomarker of efficacy need to be demonstrated.

A clinical candidate in oncology also needs to demonstrate pharmacokinetic/pharmacodynamics (PKPD) relationship and its relationship to efficacy in suitable preclinical models. Preclinical animal models do not completely predict the clinical situation. However, positive outcomes in xenograph and orthotopic models can provide confidence in the projected human dose and potentially decrease human dose projection variability. Genetically engineered mouse models (GEMMs) are useful for proof of concept in the context of clearly defined and clinically relevant genetic abnormalities (10). Understanding the mechanism of action (rapid dissociation from target, slow off-rate and irreversible inhibitors) and what driving efficacy is (e.g. AUC, Cmax or time on target) is important in predicting efficacious human dose. Properly designed exposure-effect and dose-fractionation studies in preclinical models make this possible (11).

Drug resistance is a significant challenge in oncology therapy. Reasons include: resistance to molecular agents due to mutation of the target itself (as in the case of kinase gatekeeper mutations) (12), and the activation of adaptive feedback loops (13) or alternative oncogenic pathways (14). If a clinical candidate shows promise for overcoming resistance mechanisms, it has greatly increased its probability of success in cancer treatment. Combination therapy is often considered to block multiple pathways to overcome resistance and decrease toxicities.

Treatment in Oncology almost always involves polytherapy since most treatments involve a combination of drugs, and most patients require supportive care. Therefore, drug interactions in oncology are of particular importance owing to the narrow therapeutic index and the inherent toxicity of anticancer agents and the many concomitant medications such as pain therapy, antidepressants and select anticonvulsants (15). Furthermore, the age-related decline in hepatic and renal function in many cancer patients reduces their ability to metabolize and clear drugs which can increase the potential for toxicity (16). Drug-drug interactions (DDI) cannot be well predicted by rat studies since they do not have a Cytochrome P450 3A4 equivalent to humans, which is the isozyme of P450 responsible for metabolism not only for most drugs (17), but oncology drugs in particular. Recent use of transgenic mouse models could shed some light on these predictions in addition to the standard in vitro testing for inhibition and induction (18). Yet not all DDI can be predicted, and those that can be predicted are not always avoidable. Therefore, the use of well-established models to predict DDI potential at discovery stage is essential for risk assessment (19).

Good physicochemical properties and acceptable PK are essential for clinical candidates in order to evaluate efficacy and toxicity. The projected efficacious human dose should be far less than the maximum absorbable dose in order to fully explore safety and efficacy in clinic trials. Poor solubility is often a major issue due to chemical space related to cancer targets (9), and use of an enabling formulation such as a sprayed dry dispersion is often needed to improve the clinical exposure. Recently, Selen et al. published a commentary describing a roadmap where clinical relevance is directly built into early formulation development (20). This approach is applied to four relatively common therapy-driven drug delivery scenarios: 1) rapid therapeutic onset, 2) multiphasic delivery, 3) delayed therapeutic onset and 4) maintenance of target exposure and enabled the collection of data and knowledge for the development of a dosage form that performs consistently for a patient.
Preclinical safety evaluation starts at target identification, and FHD enabling toxicology studies usually follow ICH (International Conference on Harmonization) recommendations. In addition to the routine safety issues such as target organ and off-target toxicity, the potential for reactive intermediates (RI) and/or time dependent inhibition (TDI) can be factors leading to idiosyncratic drug reactions (IDRs) or drug induced liver injury (DILI) (21). In a paper published by authors working at Genentech, ten of twelve kinase inhibitors investigated were found to undergo bioactivation to RI and could be trapped by at least one trapping agent. However, relating RI formation to clinically significant risk is challenging (22). The debate on usefulness of RI as a CS criterion for oncology, and how stringent this criterion should be, is ongoing. Many companies have published their strategies dealing with RI risks (23-25), and “avoidance strategy” in early discovery appears to be a common theme where molecules or chemical scaffold without RI issue are chosen to move forward if possible. Multiple factors need to be built in risk assessment at CS, such as predicted human dose, presence of structural alert, chronic vs intermittent dosing, major clearance pathways, $f_m$ (fraction of clearance attributed to metabolism in RI pathway), and metabolite identification of RI in hepatocytes and in vivo samples and estimation of RI body burden.

In summary, drug discovery and development require balancing a large number of desired properties, a basic reason why the process has proven difficult to “optimize”. An oncology drug candidate is notably different due to special consideration of its complex targets and disease states, the need for distinctly different physicochemical properties, and the integral use of concomitant medications in oncology. In the last 10 years many new requirements have been integrated into drug discovery. Nonetheless, optimizing the discovery of oncology therapies compared to other drugs will continue to have unique attributes and challenges.

References:


Science Fun: DCS-FG Puzzle

-Meg Landis (Pfizer)

Across
2. _____ trials are large, pivotal trials to determine safety and efficacy in sufficiently large numbers of patients
3. The “S” in SAR
4. What the Body does to a Drug
5. NDA = New Drug _____
6. Many aspects of drug development are focused on satisfying the _________ requirements of drug licensing authorities
7. An APPS Section Affiliates of DCSFG
9. Circa 2004, the FDA created the “Critical Path _______” project to guide the new drug development process
11. a personal website or web page on which an individual records opinions, links to other sites, etc. on a regular basis
12. A business-oriented social networking service with a DCS-FG page
13. Hit to lead, also known as lead _________, is a stage in early drug discovery
14. The "D" in ADME

Down
1. Developability assessments often highlight this aspect
2. What the Drug does to the Body
7. the process or stage of bringing a new pharmaceutical drug to the market once a lead compound has been identified
8. the process or stage by which new candidate medications are discovered
10. Recent Drug Discovery Webinar partner of DCSFG

Key: Please See Page 9
**Preclinical Dose Number and Its Application in Understanding Drug Absorption Risk and Formulation Design for Preclinical Species**


“...this work analyzes a large data set (>900 data points) and provides quantitative guidance to identify drug absorption risk in preclinical species based on a single solubility measurement commonly carried out in drug discovery.”

**Paediatric biopharmaceutics classification system: Current status and future decisions**

Batchelor *Int. J. Pharm* Volume 469, Issue 2, 5 August 2014, Pages 251–253

“The applicability of the biopharmaceutics system to paediatric product development has yet to be explored; this note brings together some key issues in direct extrapolation from adults into paediatric populations.”

**A non-binary biopharmaceutical classification of drugs: The ABΓ system**

Macheras and Karalis *Int. J. Pharm* Volume 464, Issues 1–2, 10 April 2014, Pages 85–90

“The ABΓ system allows the classification of all compounds into three categories (A, B, Γ) in terms of the fraction of dose absorbed”

**Prediction of the in vivo performance of enteric coated pellets in the fasted state under selected biorelevant dissolution conditions**


“Thus, using more physiologically relevant dissolution conditions, expressed through low volume and lower flow rate, and in combination with increased mechanical stress we obtained equally good in vitro/in vivo correlation as using USP IV and higher flow rates. Comparison of the dissolution results obtained with two different systems provided additional insight into product behaviour and improved prediction of in vivo performance.”

**Biorelevant media for transport experiments in the Caco-2 model to evaluate drug absorption in the fasted and the fed state and their usefulness**


“Permeability coefficients, P, of hydrophilic drugs were not affected by media composition. In contrast, P values of a series of lipophilic compounds measured with FaSSIF-TMCaco and FeSSIF-TMCaco, and reflecting transport by diffusion were smaller than those obtained with a purely aqueous reference transport medium, aq-TMCaco, following the rank order aq-TMCaco > FaSSIF-TMCaco > FeSSIF-TMCaco. The decline of permeability values was stronger as lipophilicity of the compounds increased.”

‘Stealth’ lipid-based formulations: Poly(ethylene glycol)-mediated digestion inhibition improves oral bioavailability of a model poorly water soluble drug


“Stealth capabilities were assessed by measuring the degree of digestion inhibition that resulted from steric hindrance of enzyme access to the oil–water interface. Drug-loaded lipid based formulations were assessed for maintenance of solubilising capacity during in vitro digestion and evaluated in vivo in rats”

**Towards continuous production of pharmaceutical cocrystals**

Boksa et al. Society of Engineering Science 51st Annual Technical Meeting 1–3 October 2014 Purdue University, West Lafayette, Indiana, USA

“... the Matrix Assisted Cocrystallization (MAC) product with the exact same composition resulted in considerably faster dissolution and higher maximum concentration (~5-fold) than those of the Physical Mixture (PM). The MAC product consists of high-quality cocrystals embedded in a matrix. The processing aspect of MAC plays a major role on the faster dissolution observed. The MAC approach offers a scalable process, suitable for the continuous production, manufacturing, and formulation of pharmaceutical cocrystals”
Trends in the Precipitation and Crystallization Behavior of Supersaturated Aqueous Solutions of Poorly Water-
Soluble Drugs Assessed Using Synchrotron Radiation


“Nuclear magnetic resonance spectroscopy experiments supported the supposition that polymers need to have
affinity for both the drug-rich precipitate and the aqueous phase in order to be effective crystallization inhibitors.
This study highlights the variability in the crystallization tendency of different compounds and provides insight
into the mechanism of inhibition by polymeric additives.”

Early pharmaceutical profiling to predict oral drug absorption: Current status and unmet needs


“As part of the Oral Biopharmaceutical Tools (OrBiTo) project, this review provides a summary of the
pharmaceutical profiling methods available, with focus on in silico and in vitro models typically used to forecast
active pharmaceutical ingredient’s (APIs) in vivo performance after oral administration.”

Physicochemical and Formulation Developability Assessment for Therapeutic Peptide Delivery—A Primer

Bak et al. The AAPS Journal, Vol. 17, No. 1, January 2015

“This review introduces the physicochemical, biophysical, biopharmaceutical, and formulation developability
aspects of peptides pertinent to the drug discovery-to-development interface. It introduces the relevance of
these properties with respect to the delivery modalities available for peptide pharmaceuticals, with the parenteral
route being the most prevalent route of administration.”

Science Fun Answers

Key:

DDDl: An APPS Section Affiliates of DCSFG
Risk: Developability assessments often highlight this aspect
Pharmacodynamics: What the Drug does to the Body
Distribution: The "D" in ADME
ACS: Recent Drug Discovery Webinar partner of DCSFG
LinkedIn: A business-oriented social networking service with a DCS-FG page
Structure: The "S" in SAR

Development: The process or stage of bringing a new pharmaceutical drug to the market once a lead
compound has been identified
Pharmacokinetics: What the Body does to a Drug
Blog: a personal website or web page on which an individual records opinions, links to other sites, etc. on a
regular basis
Discovery: the process or stage by which new candidate medications are discovered
Regulatory: Many aspects of drug development are focused on satisfying the ______________ requirements
of drug licensing authorities
PhaseIII: _________ trials are large, pivotal trials to determine safety and efficacy in sufficiently large numbers
of patients
Application: NDA = New Drug ______________
Initiative: Circa 2004, the FDA created the “Critical Path ______________” project to guide the new drug
development process
Generation: Hit to lead, also known as lead ____________ , is a stage in early drug discovery
Conference Update

- John Morrison (BMS)

The Northeast Regional Discussion Group (NERDG) of AAPS hosts a one-day event uniting a diverse group of pharmaceutical scientists. Typically the venue attracts over 200 participants from industry and academia interested in fostering scientific and professional interactions. The 18th annual meeting was held on Thursday, April 16th, 2015 at the Marriott Hotel in Farmington, Connecticut highlighted by two excellent keynote presentations:

Navigating the Transition from Discovery to Development: A Pharmaceutical Scientist’s View
Dr. Caroline McGregor (Executive Director, Discovery Pharmaceutical Sciences at Merck)

The Pharma Industry - How We Arrived Here, and Where We Might Be Going
Dr. Derek Lowe (Research Fellow, Medicinal Chemistry, Vertex Pharmaceuticals)

Invited round table speakers from both academia and industry provided insight and viewpoints on a variety of topics of current interest:

1) In Vitro Dynamic Dissolution Methodologies and In Vivo Prediction Power
2) The Role of System Biology in Reducing Phase II Attrition, Are We There Yet?
3) PK/PD Implementation in Biologics: Case Studies
4) Modulating Potency as a Driver to Mitigate ADME and Toxicity Liabilities
5) Applications of Analytical Techniques in Pharma R&D

Individual scientists were also provided the opportunity to present their own research efforts as either a short topic oral or a poster presentation. The NERDG meeting also encourages student participation with an academic research award session in which cash prizes are awarded to the top three graduate student oral presentations. Student competitors are judged for both scientific content as well as presentation quality.

The 2015 Executive Committee includes John Morrison (Chair, Bristol-Myers Squibb), Catherine Ambler (Chair Elect, Pfizer), Mary Tanenbaum (Treasurer, Boehringer Ingelheim), Renée Kitson (Sponsorship Lead, American International Chemicals), Anand Balakrishnan, (Posters and AAPS Liaison, Bristol-Myers Squibb), Vrushali Waknis (Short Topic Presentations, Bristol-Myers Squibb), Ayman-Al-Kattan (Round Tables, Pfizer), Michelle Nophsker (Communications Lead, Bristol-Myers Squibb) and Roy Haskell (Senior Advisor, Bristol-Myers Squibb). The NERDG annual meeting also receives generous corporate sponsorship from Boehringer Ingelheim, Bristol-Myers Squibb, Colorcon and Pfizer. Additionally at least 14 tabletop sponsors help ensure the success of this event, helping to keep the meeting amenable to most participants in the northeast with a relatively low registration fee of $85 (industry) and $50(academia).

For more information, please visit the website:
http://aaps-nerdg.org/about/

Contact us!

The intent of this newsletter is to provide snapshot of the DCS focus group, and its activities along with topics of interest and expertise

The newsletter committee welcomes comments and suggestions for improvement along with topic ideas for future newsletters.

Please feel free to contact us!

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John Morrison, PhD (email: john.morrison@bms.com)

We would appreciate hearing your comments and feedback.