Greetings fellow PHT members!

As we approach the end of the organizational year, I am heartened at how much we have accomplished in the past nine months. There are now more than 30 people participating on the Advisory Board lending a hand with programming for 2016, the membership survey, the strategic plan revision and many other tasks both small and large. There are initiatives underway to post open positions for job seekers on our website in a creative format and also to insert ads from vendors there as well. The Annual Conference in Boston this past June offered a full set of excellent programs and the Fund Development Committee raised a record amount of money to support those programs. Robin Fogel and her committee are already geared up with a full list of program ideas for the conference scheduled for next June 12-14 in Philadelphia. Sonal Shukla is likewise engaged with her committee to develop a full slate of programs for the Spring Meeting in Orlando, April 3-5.

At the Association level there has been controversy and turmoil for the past several months surrounding the future of the Association. Consultants were hired to make recommendations for a path forward and once the recommendations were written and distributed, hours of members’ time were spent reading, reviewing, and commenting on these prior to, during, and following the Annual Conference. The Association Board met to vote and agreed to “receive” the recommendations. Next step was to provide us with a “Road Map for the Future of SLA.” Only time will tell how all of this is resolved.

In closing, I would like to take this opportunity to thank all who have served on the Advisory Board this year in the multitude of tasks, jobs, and positions. Special thanks go to all the Division Chairs who preceded me and left a legacy of dedication and leadership. Very special thanks go to Chair-Elect John Chu who has stepped up to assist in many places and taken time to listen and help out wherever needed.

Being Chair of the Pharmaceutical & Health Technology Division has been a rewarding and challenging experience. Thanks for giving me this opportunity.

Cheers,
Janet
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Productivity in the Biopharmaceutical Industry: Trends in the Economics of New Drug Discovery and Development

Speaker: Joseph DiMasi, Tufts Center for the Study of Drug Development

The man behind the podium needed no introduction to the audience of dozens. People were there to see him, to hear him, to focus on his words as he presented the latest chapter in the saga of drug development.

As members of the pharmaceutical and biotechnology industry, we understand how closely our colleagues follow quality articles and data about the cost of developing new drugs and products. Every indication, every phase, has a different layer of complexities and expenses. Far too often the ill-informed members of the general public scream that drugs shouldn’t cost so much, making pharmaceutical companies millions of dollars per drug because that’s not fair. If they could listen to Dr. DiMasi’s well-laid out presentation and calm words, things would make more sense to them. After all, he is the Director of Economic Analysis at the Tufts Center for the Study of Drug Development (CSDD). With a pending article in press, the audience was about to be treated to insight not available to those outside our field.

What is so different about this pending article, this new analysis, this recent price tag? For the first time, the team from Tufts included the cost of pre-human trials in this detailed analysis. All animal testing costs, all overhead costs, and all indications for 106 investigational new drugs and biologics from 10 firms, first tested in humans anywhere in the world between the years of 1995 to 2007. The team then followed those drugs up to 2013 in terms of clinical period development, to be sure they had the most complete set of data available. Of the 106, only 5 remained “active” at the time of last data collection.

The audience on this June day were informed people. Everyone – every single person – had a pen and pad of paper in hand, ready to learn the latest. This was true because the entire presentation was given to this group before being published. The presentation we saw had not even been released on the Tufts CSDD website. One hesitates to say “totally awesome fabulous new data news,” but this it was. We were seeing what others had not yet had the opportunity to learn.

The presentation started with an understanding of the background trends, explaining the increase in New Compound Approvals from 1963 through 2013, as compared to billions in Research & Development (R&D) expenditures. Next, there was discussion about trends in New Drug Applications (NDAs) as well as Pediatric and new indications. Clinical development times, based on 3-year moving averages, show that Approval Phase times have decreased, but that it is taking longer and longer for the clinical trials phase, which translates to an overall increase in total phase times over the last 50 years. Dr. DiMasi compared the changes over time between the original and landmark 2003 study from the Journal of Health Economics, which

**NEW DRUGS NOW COST NEARLY $2.6 BILLION, SHAPING DIRECTION OF SPONSORS’ R&D EFFORTS**

*Rising R&D costs, driven mainly by increased out-of-pocket costs and higher failure rates for drugs tested in human subjects, means the average cost to develop and gain marketing approval for a new prescription medicine, a process often lasting longer than a decade, is now $2.56 billion dollars. Drug developers continue to make efforts to rein in costs, but also have responded by focusing their R&D on products for markets with more attractive investment returns.*

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**Average Cost to Develop and Win Marketing Approval for a New Drug**

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Rising R&D costs, driven mainly by increased out-of-pocket costs and higher failure rates for drugs tested in human subjects, means the average cost to develop and gain marketing approval for a new prescription medicine, a process often lasting longer than a decade, is now $2.56 billion dollars. Drug developers continue to make efforts to rein in costs, but also have responded by focusing their R&D on products for markets with more attractive investment returns.
first brought him to the attention of the SLA PHT audience (http://www.ncbi.nlm.nih.gov/pubmed/12606142). The focus of the presentation then shifted slightly, to a more recent time frame of 2000 to 2013, where much more data has been tracked.

As in previous conferences for SLA, Dr. DiMasi shared insight into how times, indeed all data, varied among indications. On average, it takes 8.5 years for a Central Nervous System (CNS) drug to finish its clinical development. This is much longer than the Anesthetic/Analgesic market, which is a mere 4.9 years in comparison. Antiinfectives (sans AIDS antivirals) is in the mid-range at 6.1 years. However, this same breakout does not hold true when it comes to regulatory approval times. Here, CNS again took the longest, at 19.5 months but Anesthetic/Analgesic took the third-longest, at 17 months. Antiinfectives took 15.1 months. The AIDS antivirals were fast-tracked over time and were approved in a mere 7.7 months, a stunning three fold difference.

What can speed a review? One factor is the entity in question being given special status such as Breakthrough Therapy, the FDA designation to expedite the development and review of drugs for serious or life-threatening conditions. This is why HIV drugs often take less approval time. Fast Track Status also helps to expedite the review of drugs to treat serious conditions and fill unmet medical needs. This is not easily obtained but will reduce approval times. Accelerated Approvals, which meet a surrogate endpoint instead of a full clinical endpoint, also have reduced approval times. Since this was a 2012 FDA regulation change, it has had essentially little impact on the overall study parameters. Priority Review is another special status meaning the FDA will take only 6 months after submission instead of the usually anticipated 10 months. As with the other three options, this is generally granted only for serious conditions and is not a common event.

To do the analysis, Dr. DiMasi patiently walked the audience through the dataset used and the methodology and descriptions of elements used to determine the fully allocated costs of new compound R&D. Compounds that lingered late in development were oversampled in order to increase the amount of information for late development stages. The team then weighted the results to reflect the population distribution before conducting final analysis. In fact, multiple elements were used to validate their data. Out-of-pocket clinical costs, development times, cost of capital, even out-of-pocket discovery research and preclinical development costs, were added into the equations. All methodology is consistently documented by Dr. DiMasi’s team should questions arise about any given element. Even caveats were discussed, as no data is ever perfect. To acquire the pre-human R&D costs, the analysis team used the annual company biopharmaceutical R&D expenditures from 1990 to 2010, using several methods to break out parts in order to form a reasonable and coherent amount. For instance, the reason out-of-pocket clinical costs are so important — something many naysayers do not grasp — is the time cost involved in the discovery research. To clarify, Dr. DiMasi provided the analogy of a vehicle purchase. What happened if a person paid $30K for a new car today but was unable to actually get the car for another 10 years? What is the real cost to

“Productivity” continued on page 6
that person in the intervening years? There has to be alternative transportation, and this is a cost.

The next topic covered was the path to drug cost enlightenment. Rather than delve into the details here, it is advised instead that people read the presentation available on the SLA website: https://www.sla.org/wp-content/uploads/2015/06/1546_ProductivityBiopharmaIndustry-DiMasi.pdf (as accessed 30 June 2015). There are slides about clinical period costs for investigational compounds, coefficients of variation by clinical phase, and even how the number of indications pursued may impact the time (both weighted and unweighted). Please reach out to the nice people at Tufts CSDD with specific questions.

The percentages of failures are now higher in Phase I trials, a change from the prior study where more than half were in Phase II. Stepping back, this is positive in terms of cost reductions. The earlier the failure, the less overall cost for that drug in that indication — positive news for the bottom line bean counters. Or in the words of Dr. DiMasi, “Failing faster will lower R&D costs, unless more drugs fail, then the R&D costs will be higher. It’s simple math.”

Industry watchers tout the mega-million dollar blockbuster drugs. In reality, few compounds actually have high sales. Ask any rep from IMS Health or Symphony Health to crunch the basic numbers for drugs with sales over a billion dollars. According to the Tufts teams, only 20-40% of drugs ever reach or exceed the R&D costs of development for that drug. Therefore, once a drug has been approved for one indication, many companies will pursue follow-on indications. In Phase I, a drug has a 1.41 mean number of indications; by Phase II the number reaches 3.44 indications. Follow-on indications will not extend the patent life of the ingredient but could bring on exclusivity and perhaps reformulation patents. The longer a drug sells under a brand name, the better things are for the company, with more of a chance to recoup the losses caused by the failures of other drugs.

Yes, R&D costs have continued to increase at high rates. The increase in various indications has an impact, as does inflation. Clinical approval success rates have declined significantly. This raises several questions. For example, how much is the FDA causing this by increased safety and scrutiny? Drug development times have stabilized but are still lengthy. Should industry be looking for alternative processes? What can be done to “bend the R&D cost curve” as demonstrated so clearly by the Monte Carlo Simulation Forecasts for Total Capitalized Cost per Approved New Compound (See the presentation for a bell-curve visual.)

Perhaps much of this seems logical to those of us in the industry because we see it every day as part of the process. To see the facts laid out, however, was at once fascinating and enlightening.

In the end, the witty speaker and his dry sense of humor summed up much of the presentation in one short sentence: “Success rates vary by phase, by indication, and by attention to detail.” With a higher level of detail scrutinized, costs can only increase.

As information professionals, what do we need to do to track, to follow, to stay informed? Clearly, we all need to watch what the DiMasi team says, prints and defines in order to help our colleagues and our companies take new strides forward as we all battle the ever increasing costs of developing a new drug.

Tara Breton
Health Advances LLC

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**Productivity** continued from page 5
“Shared Knowledge in Firms that Care and Cure”

Presenters: Elizabeth Arnold, Manager, Knowledge Services, Celgene Corporation; Mark Burfoot, Executive Director, Novartis

Moderator: William Cook, Manager, Knowledge Management, ADP

Presented By: Knowledge Management Division, Pharmaceutical & Health Technology Division

Sponsored by: ProQuest

Liz Arnold (Celgene) and Mark Burfoot (Novartis) provided this case study of successful KM initiatives by libraries in two companies of the biopharma industry. Co-sponsored by the KM and PHT Divisions, the session was well attended by a standing-room-only crowd, and it generated a lot of buzz before, during, and after the session among the members of both Divisions.

Novartis is one of the largest European-based pharmaceutical companies with products across a wide spectrum of therapeutic areas. Celgene is a rapidly growing US-based biotech expanding beyond oncology and delving into immune-inflammatory diseases. The speakers’ presentations and slides were very insightful and informative. The two KM initiatives also provided contrast between the types of documents covered. Novartis’ were mostly internal proprietary, whereas Celgene’s were mostly external publications. Research stages also differed. Documents were R&D-focused for Novartis as opposed to clinical trials-focused for Celgene.

It is especially noteworthy that Liz and Mark both deployed existing tools already familiar to PHT members — Quosa for Celgene and SharePoint for Novartis. Thus, this could be a cautionary tale of not being influenced by all the KM vendors’ sales pitches with their products looking for solutions. Instead the two speakers provided excellent examples of information professionals discerning and identifying business processes, then successfully making use of already deployed tools. Also demonstrated were close collaborations with an internal IT department (Novartis) and a vendor (Celgene and Elsevier).

Another critical success factor was that both Mark and Liz were able to align their KM initiatives with critical internal business functions. These functions were R&D for Novartis and Medical Affairs for Celgene, thus securing management buy-in, support, and endorsement at each company.

For more details of each case study, the readers are encouraged to download the entire slide sets of both speakers from the Annual Conference 2015 website.

Novartis Sharepoint KM initiative highlights:

- Key documents were R&D meeting minutes and compound structure-containing documents.
- Key participants in the KM process were Admin’s who generated meeting minutes.
- Multiple R&D data sources were used to start the flow to information, knowledge, and wisdom.
- End result was the ability to extract knowledge buried in a myriad of other documents.
- Significant automation was done by keying in on the document subject, meeting agenda and project codes.
- R&D-based taxonomy and controlled vocabulary were employed.
- Same process can and has been used to extract knowledge from external publications.

Celgene Quosa KM highlights:

- Built as part of the Medical Affairs portal.
- Needed an improved tool to replace Reference Manager.
- Key documents were all publications related to product clinical trials.
- Special customizations included dynamic links and custom fields within Quosa.
- Basic taxonomy was developed and used within Quosa.
- Special integration was accomplished with CCC’s Rightsphere to facilitate article distribution.
- Value-added component of evidence-based publication summaries were outsourced to a vendor also using Quosa.
- Aggressive internal advocacy and end user training were important in ensuring success.
- Two important lessons learned pointed out by both speakers included:
  - Starting with a low hanging fruit (existing business functions/processes within the company with the opportunity for improvement)
  - Starting small and not trying to solve all the problems immediately. The session convincingly proved not only how to start KM but also how to get it done right.

If there is one thing that both speakers were not quite ready to address, it was the hard dollar ROI for all the investment (tools, customization, staff time, maintenance effort) made for their KM initiatives. It is hoped that these two pioneers will be able to share that in the not-too-distant future.

John Chu
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CapLits Revisited: 1994

Though pioneering biotechnology companies such as Amgen, Genentech and Genzyme were founded in the late 1970s and early 1980s, this article from the Fall 1994 issue implies that it took until the 1990s for investment in biotech to attract the attention of major investors and large companies.

Biotechnology: Financing the Next Era of Medicine
d by Kathryn Walsh, Purdue Frederick Co.

In a stimulating session at SLA's annual meeting in Atlanta, three experts shared their insights and forecasts for the industry. The session was co-sponsored by the Business and Finance and the Pharmaceutical Divisions and was generously supported by Don & Bradstreet Information Services. The session's distinguished speakers were George McGregor, director of Information services, Chiron Corp.; Jim McCamant, editor and publisher of the Medical Technology Stock Letter, and Roger Longman, managing partner of Windhover Information Inc. The session was moderated by Kathryn Walsh, assistant director, library services, the Purdue Frederick Co.

Biotechnology has so captured the attention of investors, corporations, the media, and the general public that it is difficult to imagine a special library that will remain untouched by it. In recent years, we have seen major increases in biotechnology by organizations as diverse as Kodak, Shell Oil, Smith & Beecham, and Boston University. As more and more organizations become involved in biotechnology, librarians across a broader spectrum of institutions will need to become familiar with the language and characteristics of this industry.

As a librarian and a biologist, George McGregor set the stage for the program by explaining the basic concepts behind the science of biotechnology. In a sense, biotechnology is as old as agriculture, but recent advances in our understanding of DNA and molecular biology have led to the birth of modern biotechnology. To understand biotechnology is to understand DNA and its role in the cell. DNA can be thought of as nature's information storage and retrieval system.

The promise of biotechnology companies is dazzling, but over the past several years there have been some major disappointments. Stock prices of the industry as a whole have dropped dramatically. How does an investor profit from these companies? Jim McCamant, editor of the Medical Technology Stock Letter, discussed the techniques that analysts use to evaluate biotechnology companies.

In addition to individual investors, pharmaceutical companies and other large institutions have also played a role in funding biotechnology companies. Biotechnology has developed on a desktop and it is increasingly important. Regardless of the investment climate, the number of deals continues to grow. Roger Longman, editor of In Vivo, discussed the reasons behind this growth.

What is the information professional's role? We are frequently asked to provide information about companies. It is important to understand the purpose behind the question. Is our company evaluating a potential deal? Are we trying to understand the competition for a potential product we may be developing? Becoming familiar with the industry, its science and financial aspects, will help us to deliver better information. Biotechnology is an information-intensive industry that depends on a wide range of knowledge and ability to bring products to market and improve healthcare. As information professionals, we can play a critical role in the biotechnology revolution.

Editor's Note: This is an excerpt from a very interesting and informative article by Walsh entitled "Biotechnology: Financing the Next Era in Medicine" SLA Business and Finance Division Bulletin (Fall 1994) Issue 97-28-31.

Stipend Award Update
by Susan Katz

Our second year of the Stipend Award has had some growing pains, but we are determined to continue. Several factors have created further delays in determining the winners of the essay contest. Since we are still in the process of evaluating all the entries, we can't give any more details. Final decisions will be made by the end of September, and the winners will be announced in the next issue of CapLits.


Plans are underway for the next year's essay contest. If you are interested in helping, please contact Susan Katz.
3D Bioprinting Information Resources

3D printing in the life sciences encompasses medical devices and dental implants, both for prototyping and personalized for individual patients. Live cell and tissue printing is now used to produce “organ on a chip” for drug screening (offering reduction in the use of animal models) and important advances in assessing and predicting drug efficacy, pharmacokinetics, and safety, as well as target identification, target validation, and drug repurposing. Eventual biofabrication of organs is still nascent, but holds promise for tissue engineering and regenerative medicine. Many technical challenges remain, but ongoing efforts to validate preclinical animal and clinical data offer intriguing possibilities.

Mary Chitty, Cambridge Healthtech, Needham, MA

PubMed growth of articles 2005-2014

2005-2014 4,576% increase

PubMed “3D printing” OR bioprinting OR bioink*

OVERVIEW


http://www.nature.com/nrd/journal/v14/n4/abs/nrd4539.html

Terminology:

Relevant terms include 3D printing, additive manufacturing, biofabrication, bioprinting, bioinks. Related concepts include biomimetics, hydrogels, microfabrication, microfluidics, scaffolds and spheroids.

Biomaterials glossary & taxonomy
http://www.genomicglossaries.com/content/biomaterials.asp

Software:

Unlike plastics, where the interior of printed objects is less important, 3D printing of cells or tissues demands attention to the extracellular matrix scaffolds and vascular system.

AutoDesk, Organovo partnership

Key Technologies:

Microfluidics, lasers, nanotechnology.

Key organizations:

Wyss Institute for Biologically Inspired Engineering, Harvard University
http://wyss.harvard.edu/

Wyss organs-on-chips
http://wyss.harvard.edu/viewpage/461/

Organovo, San Diego
http://www.organovo.com/

Bioprinting companies to watch, Stem Cell Assays 2014
http://stemcellassays.com/2014/07/20-bioprinting-companies/

Announcements:

3D bioprinting information resources are scattered. The field is developing quickly, is highly interdisciplinary and technical. Knowledge of:

- Journals: 3D printing, additve manufacturing, biofabrication, bioprinting, bioinks. Related concepts include biomimetics, hydrogels, microfabrication, microfluidics, scaffolds and spheroids.
- Software: Unlike plastics, where the interior of printed objects is less important, 3D printing of cells or tissues demands attention to the extracellular matrix scaffolds and vascular system.
- Key Technologies: Microfluidics, lasers, nanotechnology.

Overall:

PubMed “3D printing” OR bioprinting OR bioink*

PubMed growth of articles 2005-2014

2005-2014 4,576% increase

PubMed “3D printing” OR bioprinting OR bioink*

http://www.organovo.com/organovo.shtml

Organovo, San Diego
http://www.organovo.com/

Bioprinting companies to watch, Stem Cell Assays 2014
http://stemcellassays.com/2014/07/20-bioprinting-companies/
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PHT Discussion List Highlights – Fall 2015

How do you connect with colleagues around the globe? The annual conference and our division meeting are both excellent opportunities to network and remain current, by attending sessions and workshops. But what about the rest of the year? When you need to consult with your peers to determine the best strategy to ensure a successful new project launch or to make that annual goal, do you turn to your PHT Discussion list for unparalleled results? Our Discussion List is only open to SLA members—a powerful benefit of membership. Contributing to discussions not only allows you the chance to build your mentoring skills, directed in particular toward those who are relatively new to our field or assuming new roles within their organizations, but you will likely pick up info-bits yourself, information you might otherwise have missed during your busy day.

So, how is the Discussion List doing? Over the past 6 months our readership has remained constant (currently standing at 480 members), even though many choose to temporarily unsubscribe while out on vacation during the summer months. The trend we saw in the Spring, averaging 1 job announcement/week has continued through September. That’s good news, indicating a healthy supply of opportunities in the bio-pharmaceutical/medical-device industries and a more stable market for information professionals. Special thanks to Cindy Crane, the DPHT Employment Chair, who makes keeping track of new opportunities extremely easy—she posts her “Position Alert” every couple weeks, selecting positions that match the interests of our division members.

A large proportion of posts over the past quarter pertain to the new initiative launched in April, “Learning Initiative Partnership” (L.I.P.) and most recently to the announcement that our SLA dues are being restructured for 2016. If you have missed any part of these discussions, check out our archives to catch up. The beauty of the Discussion List is it provides us an easy forum to stay appraised of initiatives through announcements/opportunities put to us to guide changes within our organization and division; we can move forward through an active exchange of ideas and opinions.

Benchmarking—“the process of comparison and measurement against a standard, to improve performance.” Have you set metrics to obtain benchmarks to better understand how your organization is doing compared to global industry leaders and determine the best use of scarce resources? Pose a question to your peers; it is one of the most common uses of the List. Though not formal or systematic—it is one of the easiest and certainly most affordable ways to find relevant information that will at least provide a starting point. And, you may glimpse insight into what topics are most challenging across our industry, just by reading this List.

On a personal note, my career and life gained a new layer of complexity this month with the arrival of our first grandchild. It has certainly led me to a bit of personal reflection and provided me with an additional perspective regarding what’s important, especially toward that most precious commodity: time. I leave you with this often quoted phrase, applicable regardless of whatever stage you find yourself: Carpe Diem... Life is Good!

To post to the PHT discussions, email SLA-DPHT@sla.lyris.net

View/Search the Archives by logging into http://sla.lyris.net/read/login/

Yours,

Julia Parker
Discussion List Admin, PHT

Comments/Questions? – biosleuth@gmail.com

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<tr>
<th>Advertiser</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Reviews</td>
<td>15</td>
</tr>
<tr>
<td>BizInt Solutions</td>
<td>11</td>
</tr>
<tr>
<td>Copyright Clearance Center</td>
<td>16</td>
</tr>
<tr>
<td>Informa Business Information</td>
<td>8</td>
</tr>
<tr>
<td>Think Biotech (DrugPatentWatch)</td>
<td>2</td>
</tr>
<tr>
<td>TPR</td>
<td>13</td>
</tr>
<tr>
<td>Wolters Kluwer / OVID</td>
<td>14</td>
</tr>
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