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NEWSLETTER – VOL. IX

CONTENTS

INTERPRETING CLINICAL TRIAL RESULTS WITH A HEALTHY DOSE OF SKEPTICISM

The entire paradigm of therapeutic and medical device development in the modern era is predicated on demonstrating safety and efficacy within parameters deemed appropriate by regulators like the Food and Drug Administration (FDA) and European Medicines Agency (EMA). This is proven in a series of clinical trials, known as Phase I to Phase IV studies, with each phase generally expected to demonstrate additional levels of data. This requirement for evidence generation via clinical trials contributes to the event driven nature of biopharma/medtech, creating somewhat predictable time points when sponsors can demonstrate added value in their programs with successful studies. The significance of a positive study to a share price or company valuation has had the unfortunate side effect of leading some sponsors to be less than 100% transparent in reporting the read-outs of trials, lest a hint of negative findings taint the remaining dataset. Below we lay out the archetypal road map of clinical trials and ways to be savvy to interpreting these.

GENERAL STRUCTURE OF CLINICAL DEVELOPMENT PROGRAMS

Phase I trials, sometimes known as first-in-man studies, are primarily meant to show the safety and pharmacokinetic profile (the onset, duration, and intensity of effect) of a novel therapeutic. These studies are traditionally done in healthy volunteers, and are typically not able to demonstrate efficacy. In areas like oncology, however, there may be phase I studies in actual patients that can look for preliminary signs of efficacy as well.

Phase II trials are conventionally dose-finding studies, and will test different dose levels, ideally to find the right therapeutic window of the drug, with the best combination of efficacy and safety. This can be done by taking an initial group of patients and slowly titrating up the dose of the drug over time until they experience adverse events, or by creating specified trial cohorts at different dose levels. Phase II results should importantly inform if it is even worthwhile to pursue Phase III, the costliest phase of development, or otherwise scrap a program. Once the best doses are selected from Phase II, sponsors then move on to Phase III.

The gold standard of Phase III trials is randomized, controlled, and double-blinded studies. Randomized means that patients who are enrolled in the study are divided, in a completely random fashion by someone other than the treating physician, into different arms or cohorts of the study. Controlled means that there is a comparator to the drug of interest. Comparators could be a placebo, a specific drug or regimen, or "best alternative care," which may be any one of a series of different options determined at the physician's discretion. The latter would be more

common in studies where patients have already had multiple previous treatments. The double blinded nature of the study means that neither patient nor physician know what the dose of the administered drug (or placebo). This avoids introducing bias into the study. In the case of medical devices where a surgical procedure is required, trial protocols may call for "sham" procedures to maintain the blinded nature of the study. With any luck, a Phase III trial or trials will demonstrate the appropriate levels of safety and efficacy that allow the sponsor to submit for regulatory approval. There may be multiple Phase II and Phase III trials in a given development program, depending on the therapeutic area. Any one negative trial could kill an entire development program.

Sometimes, sponsors may have less than perfect data packages that they submit for regulatory approval. When there may be lingering questions about certain aspects of the drug or device, especially around things like long term safety, regulators may still approve the application, contingent on the completion of Phase IV or post-marketing studies, to make sure the worst fears are not borne out in use among larger populations. Also of note, trials are often conducted in "perfect" patients, who often look clinically very different from patients treated in real world settings that may have other co-morbidities, and be generally less healthy than trial patients. This makes the collection of longer term evidence more pressing, as either the number of severity of adverse events may vary in a real-world population compared to the trial population.

UNDERSTANDING THE GENERAL FORMATS OF DATA READ OUTS

Sponsors have many outlets along the course of development to convey the results of trials to patients, health care providers, and investors. These range from something as simple as a press release, through poster and podium presentations at medical congresses, up to peer-reviewed publications in academic journals. Moving along that spectrum, there is increasingly more granular data, ideally shining a light on not only the good, but also the bad and the ugly.

The terse nature of press releases leaves them fraught with potential for ambiguity. At worst, sponsors may simply report positive efficacy trends, without noting the statistical significance as defined by a p-value, and with no mention of adverse events. The measure of efficacy can also be poorly defined; some questions a savvy reader should ask are[1]:

- Is a positive signal from a primary endpoint or secondary endpoint? The primary endpoint is the most important hypothesis the trial sought to test.
- Was the p-value and form of statistical analysis associated with that endpoint prespecified? A prespecified statistical analysis is less vulnerable to selective p-value hacking once data has been unblinded.
- Were patients excluded from the efficacy analysis? If so, why? For example, is it just a particular subgroup or subgroups and not the entire enrolled population? Excluding patients may have the effect of only cherry picking the best-performing patients for the data analysis.

Moving up the chain, abstracts that are submitted to medical congresses as either poster or podium presentations are commonly peer-reviewed, albeit not with the same scrutiny that would come with a full journal article. These presentations typically have more details on the methods and results as compared to press releases. The public presentation of data by ether principal investigators or the scientists/clinicians driving a development program also provides at least some public venue for questions and answers.

There is a smattering of other outlets for partial data disclosure – these include corporate investor decks presented at investor conferences, so called "R&D days" hosted by companies, and sponsored satellite symposia at relevant scientific and medical conferences. These should generally be approached with the same caveats as above given the selective disclosure.

While it depends on the journal, the final publication of trial data is typically a much more robust and trustworthy source than the original press releases of the same data.

[1] https://www.sciencedirect.com/science/article/pii/S2451865416301132

Not only are there multiple authors on a given manuscript, many of whom are unlikely to be employees of the sponsor, there are also multiple peer reviewers, whom are experts in the same field and required as part the journal's submission and editorial process. In addition, there are the journal editors themselves who are the final gatekeepers of the manuscript. In the event of particularly novel or noteworthy findings, journals may invite another key opinion leader in the same field to write an accompanying editorial to help put the findings, both good and bad, into perspective as part of the same journal issue. Often newly published articles may be open to comments from anyone interested in submitting them, which sometimes serve the purpose of poking holes in analyses or conclusions.

Full statistical plans and trial protocols may be included as appendices to the main journal article, which can be rich sources of information, but can be dense with jargon for non-experts. It is best to do a full read of not only the full manuscript but also those appendix items, and not simply rely on only the abstract or a third party summary, as these might be no better than the original press release. It is often a matter of years from the first press release to the final publication of the same data set.

OTHER TRIAL DESIGNS

All of the above is based on very conventional clinical program designs, and there are some exceptions. For example, certain late stage cancers with a precision medicine biomarker, or other genetically defined rare diseases, have utilized much smaller clinical programs to gain regulatory approval, moving from a combined Phase I/II trial to a relatively small Phase III. This is due to the inability to recruit patients for large trials from a natural small pool, and in some cases, the highly targeted nature of the therapy allows for statistically significant demonstration of efficacy with a small trial size. There is also some interest in the use of basket trials to test the effect of one drug that targets a single mutation but in a variety of tumor types, or umbrella trials, that have many different arms within one trial. These designs come with different statistical considerations. Though the designs of clinical programs may vary, the platforms for presenting data are otherwise no different, and the same healthy dose of skepticism, if not more given the smaller trial sizes, should be applied to the interpretation of those results from press releases up to and including journal articles.

- by Christine Livoti

DEERFIELD AND OXEON COHOST THIRD ANNUAL BREAK INTO THE BOARDROOM PROGRAM

On April 11th and 12th, Deerfield and its co-sponsor, Oxeon Partners, hosted the Third Annual Break into the Boardroom (BiB) program in New York City. This day-and-a half-event is the cornerstone of BiB, which was formed three years ago to help promote and cultivate greater gender diversity within boardrooms throughout the healthcare ecosystem.

We featured the 2017 edition of this event in a prior newsletter (March, 2017) but would like to refocus attention on this important initiative and report on the program's increasing traction and impact.

As it did last year, the 2018 BiB program brought together over 40 accomplished female speakers and board-ready senior executives from across the healthcare universe to discuss important fundamentals of governance, to explore key strategies for identifying, securing and evaluating board opportunities and to network among an elite group of female leaders. Participants brought an array professional experiences including roles as CEOs, CFOs as well as executive level marketing, regulatory, clinical, legal and human resources leaders. The women came from a similarly diverse range of industry subsectors, representing companies from the pharmaceutical, biotechnology, payer, provider, and HCIT spaces. This mix ensured a great cross section of perspectives and created exciting conversations among members of the healthcare ecosystem that don't ordinarily get to interact. Above all, the experience, commitment and enthusiasm emanating from the group affirmed their board readiness.

As we recap this year's event, three years into our BiB initiative, several things are clear. First, there remains an imperative to drive change – we are still a long way from

our objective of more heterogenous boardrooms. For instance, across the 20 biotech industry start-ups that raised the most venture capital dollars during the first six weeks of this year, 87% of the collective board members were male. Six of these start-ups had no female board members at all. Second, our participants are deriving value from the content and networking opportunities associated with our program, and by promoting greater awareness of the issue across our broader group of stakeholders we are seeing equally important, albeit less direct, benefits. Just getting a CEO or board to stop and realize that their leadership team or boardroom lacks diversity can be an important catalyst for change. Third, we are starting to see some tangible evidence of impact. Our program is directly or indirectly responsible for 10 new female board roles. In the coming year we plan to develop some more concrete metrics of success to hold ourselves accountable and we look forward to communicating increasing evidence that we can make a difference.

In closing, we credit many of our CEO relationships with having helped to identify and sponsor travel for our BiB nominees, which helps ensure a high caliber participant group with engaged mentors willing to support and nurture the women's governance aspirations going forward. As many of our readers may be in a position to help identify and sponsor candidates in the future, we encourage you to reach out with any recommendations for the 2019 edition of our BiB program. Similarly, we welcome the opportunity to connect our BiB alumni with board opportunities outside of our own portfolios, and would be happy to provide suggestions for board openings where you may be in a position to influence the slate of candidates.

Please send BiB inquiries to Leslie Henshaw at lhenshaw@deerfield.com.

2018 BiB Participants. Photo by Studio Brooke

PEER-REVIEWED ABSTRACTS

As part of Deerfield's mission of advancing healthcare, the Deerfield Institute is committed to publishing its proprietary research in peer-reviewed, open access scientific journals. Below is a selection of some of our recently published work. More information on the Deerfield Institute, and copies of certain past publications are available on the web at Deerfield.com/Institute.

JOURNAL OF PHARMACY TECHNOLOGY

TREATMENT SEQUENCING IN ADVANCED BRAF-MUTANT MELANOMA PATIENTS: CURRENT PRACTICE IN THE UNITED STATES

CELINE AUDIBERT, MARK STUNTZ, DANIEL GLASS

ABSTRACT

Background: Treatment of advanced BRAF-mutant melanoma has changed dramatically in the past 3 years thanks to the approval of new immunotherapy and targeted therapy agents.

Objectives: The goal of our survey was to investigate when immunotherapy and targeted therapy are used in the management of advanced melanoma patients and whether differences exist between the types of setting.

Methods: Oncologists from academic centers, community-based centers, and private clinics were invited to participate in an online survey. Survey questions addressed the proportion of BRAF-mutant patients per treatment line, proportion of patients on targeted therapy and immunotherapy available in the United States, and reasons for prescribing each drug class.

Results: A total of 101 physicians completed the survey, of which 47 worked in a private clinic, 33 in an academic center, and 21 in a community-based center. Academic center participants tended to see more severe patients ($P < .001$) and had more patients in second-line treatment than participants from other setting types. In addition, academic center physicians had more patients in clinical trials ($P < .001$), and they prescribed the ipilimumab and nivolumab combination more frequently. In terms of sequencing, all participants used targeted therapy for severe or rapidly progressing patients and immunotherapy for those who were less severe or slowly progressing.

Conclusions: The findings illustrate the differences in treatment approach per type of setting, with patients in academic centers more likely to receive recently approved products or to be enrolled in clinical trials than those in community-based settings.

IP CORNER

Intellectual Property (IP) is a vital asset to any emerging company in the healthcare space. Here, we highlight noteworthy trends and events in the IP realm with implications for both young and established healthcare companies alike.

WHAT MAKES A GOOD PATENT?

Patents are filed for various strategic reasons and sometimes observers have difficulty discerning patent quality. What makes a good patent? There is no universal answer or formula. Reasonable people can look at the same patent and disagree on whether the patent is good or not. However, in the case of therapeutic patents, experimental data is vital to patent quality.

Unlike other types of patents, patents on therapeutics should have some experimental data in order to withstand challenges. In one case, Dr. Bonnie Davis invented a treatment for Alzheimer's disease solely while reviewing the literature. The literature described that galanthamine had anticholinesterase properties. The literature also described an increase in short-term memory in dogs after administering galanthamine and a correlation between Alzheimer's disease symptoms and a reduced level of acetylcholine in the brain. Dr. Davis deduced that galanthamine can be used to treat Alzheimer's patients, and she was correct. She filed for a patent using prophetic examples, and the patent was granted on May 5, 1987. The experimental proof of her theory was completed two months later in July of 1987. In 1995, Dr. Davis licensed the invention to Janssen. Generic pharmaceutical companies seeking to market generic versions of Janssen's drug successfully challenged the validity of this patent. The Federal Circuit affirmed the invalidity determination by the district court because relevant animal testing experiments were "not finished…by the time the '318 patent was allowed". Judge Dyk wrote that "[t]ypically, patent applications claiming new methods of treatment are supported by test results," and "under appropriate circumstances, . . . the first link in the screening chain, *in vitro* testing, may establish a practical utility for the [pharmaceutical] compound in question." This case highlights the crucial importance of data to the validity of therapeutic patents. *In re '318 Patent Infringement Litigation* (Fed. Cir. 2009).

The next consideration is how much data should be included in the patent application. Generally, broader coverage requires more data. In any case, more data is better, but this creates a dilemma. On one hand, the U.S. has a "first inventor to file system" – the first to file gets the patent. Wait too long to accumulate data and somebody else may get the patent first. File before you have sufficient data and the application may get rejected, or a weak patent may get issued that cannot withstand subsequent challenges. The latter comes with the wasted costs of the developing a therapeutic product only to see the benefits go to generics. A fact finder may find that there was insufficient proof that the invention would work for the intended purpose. For Star Trek fans, a patent application may describe a tricorder, but without more – it is still only science fiction. Even when credible, the details must be thorough enough to allow others to copy the invention after the patent expires. Finally, when very little data appears sufficient, a fact finder may view the invention as obvious. The decision on the quantity and quality of data needed is a balancing act usually decided with the help of counsel who is up-to-date on industry standards.

A patent applicant is required to submit enough data to show the inventor is in possession of the invention, the invention will work for the intended purpose, and that others will be able to practice the invention without undue experimentation. The level of data required in the patent application depends on the nature of the invention, but all therapeutic patents should have some data. A patent attorney helps to determine the sufficiency of the data by reviewing court cases where similar patents were upheld or invalidated. In many cases, it is still an educated guess. However, based on the current interpretation of the law, it is prudent to err on the side of having more data, especially in the case of therapeutic patents.

- by Mark Shtilerman, Senior Counsel

CAUGHT OUR EYE

The FDA finalized two guidances for drug and device manufacturers to clarify the agency's position on how they can safely communicate product information to payers consistent with the information in a product's label. The guidances are a response to a series of court losses and settlements related to off-label product promotion and whether those communications are protected by the First Amendment. The agency views payers, formulary committees, and other similar entities as "sophisticated parties" that are better able to interpret and evaluate product information compared to the general public. *Regulatory Affairs Professional Society*

The Centers for Medicare & Medicaid Services (CMS) released a redesigned version of its Drug Spending Dashboards, aimed at shedding light on manufacturers who have been increasing the prices of their drugs used by Medicare Part B (outpatient), Part D (drug benefit), and Medicaid beneficiaries. CMS noted it spent 17% ($109 billion) of its total budget on prescription drugs in 2012, while it spent 23% ($174 billion) of its total budget on prescription drugs in 2016. *CMS*

In an atypical move, a multi-stakeholder group of patients, clinicians, payers, health technology assessment groups, regulators, and manufacturers created a consensus set of core outcome measures for hemophilia trials. They are meant to be a minimum set of outcomes to include in hemophilia gene therapy clinical trials, of which there are several pipeline candidates for both hemophilias A and B. It is hoped the shared core set will provide for adequate inclusion of patient perspective, while allowing for fair comparisons between alternative treatments in determining the overall effect of these gene therapies. *Center for Medical Technology Policy*

The first of a new wave of migraine therapies earned FDA approval in May 2018. Aimovig, made by Amgen and Novartis, is a calcitonin gene-related peptide (CGRP) inhibitor, approved as a once-monthly injection for migraine prevention. Many industry watchers, including cost watchdog ICER, expected CGRPs to become the next class of "budget busters" for pharmacy benefit managers and managed care organizations, if not also patients themselves. However, Aimovig launched with a list price of $6,900, compared to an initial placeholder target price of $8,500 used by ICER in its first cost-effectiveness review. With the lower launch price, and assuming a 27% discount "reflective of typical rebates and discounts to reach a net price of $5,000" ICER's analysis found Aimovig's cost-effectiveness to be substantially more favorable. *ICER*

Biosimilars remain an area of interest owing to their potential to reap significant cost savings to the healthcare system and competitive threat to their branded counterparts. Yet some five year in to the US' biosimilar program, the number of rejections far outweigh the number of approved biosimilar products. Sponsors have publicly disclosed 23 original biosimilar applications since the program began in 2013, with 10 approvals and 12 complete response letters (CRL) to date. The number of CRLs may be even higher as some sponsors may not have disclosed submissions or their outcomes. *Pink Sheet*. For a deeper dive into biosimilars, please see the September 2017 issue of this newsletter.

A recent report from the US government's Office of Inspector General (OIG) looked at drug costs borne by Medicare Part D, the drug benefit portion of Medicare. The report found a 77% increase in total reimbursement for all brand name drugs in Part D from 2011 to 2015, despite a 17% decrease in the number of prescriptions for the same drugs. Despite manufacturer rebates, reimbursement for those same drugs increased 62% in the same time period. Those rate increases occurred six times faster than inflation, with twice as many Medicare beneficiaries experiencing out of pocket costs of at least $2,000 per year for brand drugs. *OIG*

The FDA plans to reorganize its Office of New Drugs to be able to better handle the next wave of application reviews. By its own calculations, this will allow the agency to be at least 20% more efficient in the review process. The proposed plan calls for 30 review divisions, up from the current 19, to be grouped into nine offices, up from the current five. This includes a split of the current hematology and oncology division into two, as well as splitting the current gastroenterology unit into gastroenterology, hepatology and nutrition, and inborn errors of metabolism and rare diseases, among others. *BioCentury*

DEERFIELD FOUNDATION

The Foundation has formed 39 partnerships and invested or committed approximately $36 million for the advancement of children's health in its 10 years, ranging from health clinics in Nepal to a mobile medical home for children in the South Bronx. In this newsletter we would like to highlight just one of the organizations that we feel is helping us fulfill our mission of advancing healthcare. We are proud to be critical supporters of The St. Boniface Haiti Foundation.

THE ST. BONIFACE HAITI FOUNDATION

Mission:	The St. Boniface Haiti Foundation (SBHF) provides essential health services to the people of Southern Haiti, especially the most vulnerable. SBHF is committed to building a comprehensive, efficient, and resilient health system that provides high quality care. SBHF believes that ensuring access to life-saving and life-changing health services is a critical component to building strong and productive communities.
Partner Since:	2016
Description:	St. Boniface Hospital is southern Haiti's only affordable, reliable, and comprehensive surgical program. By sustaining a robust health care system, SBHF works hard to create solutions to the problem of difficulty in accessing care. This difficulty results in children coming to health facilities with advanced stages of illness.
Total Funding:	$125,000
The Deerfield Perspective:	Deerfield started its partnership with SBHF in the aftermath of the destruction caused by Hurricane Matthew, which devastated the nation in October of 2015. Haiti is one of the poorest nations in the Western Hemisphere with major geographical barriers that cause health providers extensive problems granting access to the full population. Haiti lags in almost every key pediatric health indicator, with the highest infant mortality rate, the highest under-five mortality rate, and the highest prevalence of undernourishment in the Western Hemisphere. SBHF has a highly qualified brick and mortar hospital and an expansive network of mobile clinics to battle the lack of access to transportation in the country. With its strong management team and effective tactics, Deerfield has been very impressed with the results provided in a country in dire need of health care support.
SBHF Perspective:	St. Boniface Hospital is the only comprehensive provider of medical services that are accessible to all 2.3 million people who live on Haiti's southern peninsula. Children are particularly vulnerable to a lack of access to health care, and with the Deerfield Foundation's support the St. Boniface Haiti Foundation has been able to meet the need of every child who comes to the hospital seeking care.
Most Recent Projects Funded:	Provide pediatric surgical and hospital supplies to support pediatric services at St. Boniface Hospital (in Fond-des-Blancs) and the Villa Clinic. ▪ Deerfield has been providing funds to assist the hospital in providing its pediatric services at St. Boniface Hospital. The results have been very impressive and have consistently exceeded our goals. From November 1, 2017 through March 31, 2018: – SBHF's surgical team performed 139 surgeries for children under 15 years of age and performed critical surgical care to 271 pediatric patients over one year. – 29 children were treated at the SBHF's inpatient nutritional care program, the Nutritional Stabilization Unit (USN). 55 children benefited from the community-based malnutrition program where community health workers and nurses monitor and provide weekly supplementary nutritional assistance. – SBHF's hospital-based outpatient clinic for moderate acute malnutrition (MAM) saw 18 children under five years of age. ▪ The SBHF surgical team has made significant strides in decreasing pediatric surgical infections and complications, and therefore mortality, by knowing what complications are common and planning to address those complications early on. ▪ St. Boniface Hospital and the Villa Clinic have provided 5,004 and 870 pediatric consultations, respectively. SBHF is on track to meet their goal of seeing 14,960 pediatric patients over one year.

NEWS YOU MAY HAVE MISSED

We've been busy at Deerfield the last few months! Here is a sampling of some of what we've been up to:

Bridge Medicines Appoints Louis M. Renzetti, Ph.D., As Chief Scientific Officer
April 03, 2018
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Deerfield Leads Investment of up to $50 Million in Sollis Therapeutics' Innovative Solution for Sciatica Pain
April 12, 2018
Read More

Northwestern University and Deerfield Management launch Lakeside Discovery to provide tomorrow's solutions in healthcare
May 31, 2018
Read More

Ablexis Targets Market Expansion Opportunities for AlivaMab Mouse Following Acquisition by Deerfield Management and the Founding of AlivaMab Discovery Services
June 21, 2018
Read More

NEWS FROM OUR FOUNDATION PARTNERS

Our Deerfield Foundation Partners are hard at work advancing children's health. Below are some brief updates from a few of them:

Muso Study Signals New Hope for Universal Health Care and Child Survival
March, 12 2018
Muso published results of the pilot phase of their study of community health workers in peri-urban Mali in *BMJ Global Health*, showing a child under five mortality rate of 0.7%. This is the lowest rate in sub-Saharan Africa in the last five years, and also lower than the same mortality rate in the United States. Coverage of the study was featured in *Forbes* and the *Financial Times* (paywall) or the full paper can be found here.
Read More

Living Goods and Last Mile Health Selected for The Audacious Project
April 12, 2018
Living Goods and Last Mile Health were selected for The Audacious Project, a new model from TED that supports new models to inspire change at scale. Together, the organizations will deploy 50,000 digitally empowered community health workers across six countries in both East and West Africa over the next for years, starting with Kenya, Uganda and Liberia. These CHWs are expected to provide healthcare to 34 million people. Coverage was featured in *Devex* and *Business Insider*.
Read More

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