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FEBRUARY

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Lilly and Life for a Child EXPAND PARTNERSHIP

Lilly, Life for a Child, and Beyond Type 1 advance access to diabetes care in resource-limited countries.

More than 1.8 million children and young adults under 25 years old have Type 1 diabetes, yet many don't have access to the life-saving treatments they need, including insulin. In recognition of the centennial anniversary of the discovery of insulin, Eli Lilly and Company and Life for a Child (LFAC) are significantly growing their long-term partnership to expand access to diabetes care from approximately 23,000 youth in 2020 to approximately 150,000 in 65 resourced-limited countries over the next 10 years and improve management outcomes in all countries helped. Global diabetes nonprofit Beyond Type 1 will further support the expansion of Life for a Child's programming by providing educational resource development alongside strategic communications support to amplify their critically important work.

Since 2009, Lilly has donated 2.4 million vials of insulin to LFAC, but as the global prevalence of diabetes has continued to grow over the last decade, especially amongst vulnerable populations, so too must the commitment. As part of this partnership, Lilly will provide mealtime and basal insulins and reusable pens, as well as covering the costs associated with arranging, packing and shipping to countries in conjunction with Direct Relief.


Elizabeth Apelles

Greater Than One EXPANDS ITS BRAND


Mike Hartman

Greater Than One (GTO) has launched its new "Better. Believe It." branding and philosophy for the future model of healthcare marketing. Focused on data, content, and media, GTO seeks to close the loop and level up healthcare brand experiences across all audiences.

"It's been said that digital has become so efficient that it's boring," says Chief Creative Officer Mike Hartman. "The notion of the right message at the right time in the right place has resulted in even more noise. Constant inundation. With a lack of cleverness or memorability. Creativity has become compromised, and brands are not able to fully deliver on human, relationship-building experiences. Our model is not only smarter but exponentially streamlines the process."

This new branding aims to aggressively propel the company into the next decade. Not just by challenging the status quo, but by bringing something better to the table: to purposefully, personally, consistently, and efficiently build and distribute brands.

The agency's new campaign also elaborates on the benefits of having a global footprint while still maintaining independence. Founder and CEO Elizabeth Apelles notes: "It was time that our website and branding reflect the results-driven work that we produce every day. 'Better. Believe it.' speaks to the moment but also where we are headed." Ms. Apelles is a 2009 PharmaVOICE 100.

Digital-Savvy Companies MOST RELEVANT

Before the COVID-19 pandemic, a paradigm shift towards digitization was already underway across the sectors. However, the pandemic has further accelerated the transformation, which is evident by the marked growth in spending toward digitization by businesses. Against this backdrop, companies with agile digital strategies will be able to reinvent their business models and stay relevant to customers in post-pandemic era, says GlobalData, a data and analytics company.

Sudheshna Karukula, senior disruptive tech analyst at GlobalData, comments: "Remote work, omnichannel commerce, contactless interactions, and the consumption of digital content emerged as the key growth areas during the pandemic. This has shown the difference between the business models of digital leaders and laggards across industries, reiterating the trend — digitize or perish."

For instance, pharma companies investing in AI and telemedicine such as BenevolentAI and Teladoc have a significant positive impact. BenevolentAI's investments in AI for drug discovery and development have seen some success. It was able to narrow down potential candidates to six against COVID-19, where rheumatoid arthritis drug baricitinib stood the most promising and approved by the FDA.

Evofem Launches DTC CAMPAIGN FOR PHEXXI

In February, Evofem Biosciences launched Get Phexxi, a national direct-to-consumer (DTC) campaign aimed at broadening awareness of its non-hormonal, use-it-only-when-you-need-it birth control method, Phexxi.

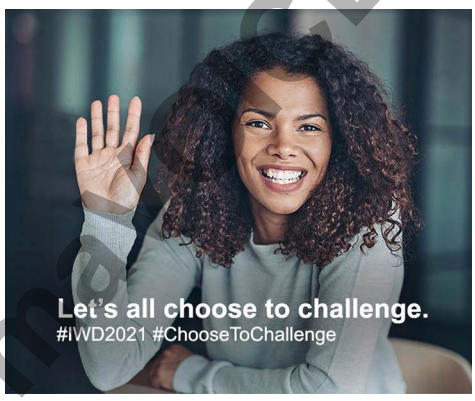
Approved by the FDA in May 2020, Phexxi is an innovative non-hormonal contraceptive method created for women. With 21 million women in the United States at risk for pregnancy who are not using hormonal contraception, the time is right for the Get Phexxi campaign to educate women about this innovative birth control option.

The DTC campaign "Get Phexxi" highlights some of the struggles women face when choosing among the many available methods of contraception, whether it's the lack of control with condoms, constant daily use of the pill, or abstinence required for cycle tracking.

The campaign highlights some of the struggles women face when choosing among the many available methods of contraception, whether it's the lack of control with condoms, constant daily use of the pill, or abstinence required for cycle tracking. The women featured in the commerical represent the real-life drawbacks that Phexxi may help eliminate as a hormone-free, on-demand birth control method.

The Get Phexxi campaign, in addition to a national commercial across broadcast, connected, and streaming television networks, will extend broadly to reach women across numerous other touchpoints through a highly targeted and multipronged digital and social media plan, as well as reach consumers at the point of care.

"In our market research, we heard repeatedly from women that they are frustrated with the birth control methods previously available to them, which left them fed up with side effects and lack of control," says Evofem Biosciences' CEO, Saundra Pelletier. "With half of all pregnancies in the U.S. unplanned, there is a clear need for additional, innovative birth control methods. This marketing campaign is designed to bring awareness to how Phexxi can fill the unmet needs of millions of women." Ms. Pelletier is a 2020 PharmaVOICE 100.



International Women's Day 2021

International Women's Day is a global day celebrating the social, economic, cultural, and political achievements of women. The day also marks a call to action for accelerating gender parity. Significant activity is witnessed worldwide as groups come together to celebrate women's achievements or rally for women's equality.

Marked annually on March 8th, International Women's Day (IWD) is one of the most important days of the year to: celebrate women's achievements, raise awareness about women's equality, lobby for accelerated gender parity, and fundraise for female-focused charities.

The 2021 theme for International Women's Day is #ChooseToChallenge. A challenged world is an alert world. Individually, we're all responsible for our own thoughts and actions — all day, every day. According to the website, we can all choose to challenge and call out gender bias and inequality. We can all choose to seek out and celebrate women's achievements. Collectively, we can all help create an inclusive world. From challenge comes change, so let's all choose to challenge.

Individuals and organizations are invited to send in their #ChooseToChallenge images, which will be shared from around the world in the lead up to International Women's Day 2021. So strike the #ChooseToChallenge pose with your hand high to show your commitment to choose to challenge inequality, call out bias, question stereotypes, and help forge an inclusive world. For more information, visit https://www.internationalwomensday.com/theme.

Medable Expands PATIENT ADVISORY COUNCIL


Jennifer McNary


Sumaira Ahmed


Dr. Gaurav Dave


Allison Kalloo


Paul Kidwell

Medable, which has a leading cloud platform for patient-centered drug development, has added four new members to its Patient Advisory Council (PAC). The PAC advises Medable and its biopharma customers on ways to improve patient access, experience, and outcomes in clinical trials. The newest members are long-time advocates, patients, and caregivers dedicated to making trials accessible and inclusive for all, regardless of geography, income and race.

Established in February 2020, Medable's PAC played a vital role over the past year advising Medable teams on product development, patient preferences and key performance indicators. The PAC also advised Medable's pharma and biotech customers on clinical trial deployments – providing advice, evaluating workflows, reviewing communication, testing usability, and improving retention for specific trials.

"No matter how a trial is conducted, it's imperative that practicality for patients is considered from the beginning," said Jennifer McNary, chair of Medable's PAC and a long-time patient advocate with 15 years of clinical trial experience. "How does the trial fit into the patient's life? Does it work for their caregiver? What would improve their access and experience? Each of us brings a personal patient connection into every study, even though patients may now be using technology to engage in trials remotely from home."

The PAC also recently expanded its reach by recruiting 15 members for its Patient Champion Network (PCN), which brings additional advocates with specific experiences into the process to consult on specific projects. Patient Champions allow the PAC to tap a wide variety of skill sets and experiences, as well as geographic and demographic diversity.

New PAC members include:

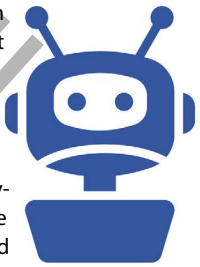
Sumaira Ahmed is currently a marketing director at Brigham & Women's Hospital in Boston. Shortly after being diagnosed with sero-negative Neuromyelitis Optica Spectrum Disorder (NMOSD) in 2014, she founded The Sumaira Foundation to raise global awareness and find a cure for NMO. Before working in marketing/public relations, Ms. Ahmed worked as an actress/model in Bangladesh and India, starring in numerous music videos, a documentary and an English-language independent film.

Gaurav Dave, M.D., is an associate professor of medicine, associate director of the Center for Health Equity Research, and director of Abacus Evaluation Consulting at the University of North Carolina at Chapel Hill. He has more than 15 years of clinical, public health research, and evaluation experience. His research focuses on reducing health disparities associated with cardiovascular diseases.

Allison Kalloo, MPH, is a patient recruitment specialist and the founder of Clinical Ambassador, iParticipate, and CliniVIVRE, which are aimed at expanding minority access and impacting diversity, equity, and inclusion in clinical research. With a personal mission to bridge cultural divides and break the engagement stalemate in clinical studies, Ms. Kalloo now leads a team to deliver culturally relevant, patient-centric communication solutions to make sense of science, support study participation from front to back, and survey the candid impressions of real patients and the research-naïve lay public. Ms. Kalloo a 2012 PharmaVOICE 100.

Paul Kidwell is a Boston-based public relations and patient advocacy consultant, providing media relations and patient engagement support for biopharmaceutical companies, and a rare disease podcaster. He has been a Parkinson's caregiver since 2007. Paul's patient advocacy experience is extensive, having developed and supported patient ambassador programs; patient, caregiver and oncology nurse leadership councils; and patient storytelling. In 2013, Mr. Kidwell and MassBio co-created the Patient Advocacy Summit, an event that focuses on the intersection of patient advocacy and the biotech industry, featuring keynote presentations, panel discussions, case studies, and live patient storytelling. Mr. Kidwell also hosts the podcast Openly Rare with Paul Kidwell which fo-

Bots & COVID-19



According to a recent report from CMI Media Group, doctors are not only busy fighting COVID, but have also have taken on the role of fighting misinformation about the virus and vaccines. CMI's social listening data found that physicians have had to step up as de facto influencers, educating and providing a trustworthy resource. A major adversary has been a mix of bots and mis-informed individuals – CMI found much of the misinformation doctors had to fight was coming from bot accounts, which continue to wreak havoc in 2021, as well as a heightened need for education.

GSK Ranks No.1 IN THE 2021 ACCESS TO MEDICINE INDEX

The Access to Medicine Index (ATMI) published its 2021 report ranking GSK again No. 1 among 20 of the world's largest pharmaceutical companies. The independently developed, investor-backed Index is based on progress companies are making in improving access to medicine in 106 low- and middle-income countries and in relation to 82 diseases, conditions and pathogens.

GSK's overall ATMI score improved from the 2018 Report, reflecting the company's clear access-to-medicine strategy embedded within overall company strategy, and the application of its scientific innovation to address global health priorities — with the largest R&D pipeline compared to peers targeting priority diseases impacting people in low- and middle- income countries.

The report also further highlights the significance of cross-industry and cross-sector collaboration in improving the health of people in developing countries. A number of collaborations aligned to GSKs Global Health priority areas were recognized, including the development of pediatric formulations of dolutegravir for HIV; licencing its tuberculosis vaccine candidate to the Gates MRI for development and use in low-income countries; and collaboration with WHO, PATH and Ministries of Health to implement the RTS,S vaccine for malaria in Ghana, Kenya, and Malawi. The Index also recognizes the breadth of ViiV Healthcare's voluntary licensing for dolutegravir and the impact of GSK's work with GAVI.

SPEAK Out

Provided by: Calyx

Making your trial breakthrough:

How imaging can make — or break — your accelerated trial

Peter Steiger, PhD, Chief Scientific Officer, Calyx, and **Elizabeth Dalton**, Vice President, Technical Solutions, Calyx

Breakthrough Therapy studies evaluate the effects of therapies on the most severe diseases, where patients have irreversible morbidity or mortality [IMM] or symptoms that represent serious outcomes of their sickness. The pressure to deliver quality data is immense because the cost of not delivering can result in patient deaths that may have been prevented.

The race is on

Earning the FDA's prized Breakthrough Therapy designation is just the beginning of the race, one that likely requires the use of an imaging surrogate for preclinical evidence or accelerated approval. For researchers who receive the coveted designation, this means getting clinical trial imaging done right, and fast.

But meeting the rigor of the FDA's accelerated review process can be complicated. When medical imaging is required, sponsors need to confidently navigate numerous challenges they'll face from an operational, regulatory, medical, and scientific point of view. And they must have the tools and processes in place in order to be able to move quickly.

"Unanticipated and complex imaging data may need to be submitted within just a few weeks, so having a solid process in place to ensure rapid, high-quality delivery is critical."

Proven processes and scalability are key

The design and demands of a Breakthrough Therapy trial can change practically overnight. Sponsors need to quickly collect patient images, onboard and train expert readers, and be prepared for the FDA's rolling review process. This is where individual application sections are sent to the FDA upon completion, as opposed to holding individual sections until the application is complete. In Breakthrough Therapy trials, validated imaging exports are likely required at each stage of the rolling review.

Breakthrough Therapy trial sponsors also need the flexibility to include both known and exploratory imaging biomarkers. We've seen Breakthrough Therapy trials require multiple, separate criteria per patient. Unanticipated and complex imaging data may need to be submitted within just a few weeks, so having a solid process in place to ensure rapid, high-quality delivery is critical.

Even more important, however, is the ability to quickly scale the number of readers who are trained and able to join the image review team when a study accelerates. Each reader needs to be specialized in the therapeutic area, trained on the trial's imaging charter and on proper application of the analysis criteria, and committed and available for the duration of the study. A plan for adjudicating disagreements and monitoring inter- and intra-reader variability also needs to be in place.

"A study planned for a few dozen patients can quickly scale to over one thousand, and the reader team may need to grow tenfold."

Sponsors need to be prepared for potential, massive scope changes based on changes to the protocol, FDA requests, or need for additional studies. We have seen phase 1 trials evolve into the design of a complex phase 3 study, all through multiple protocol amendments. A study planned for a few dozen patients can quickly scale to over one thousand, and the reader team may need to grow tenfold.

Conclusion

These examples depict how every aspect of a trial is heightened, and how the challenges of medical imaging need to be addressed, with confidence, when a compound is designated a Breakthrough Therapy.

Everyone involved – from project managers to readers and scientists – needs to appreciate the importance of delivering flexibility, speed, and data quality that meet FDA standards in order to gain approval and bring important Breakthrough Therapies to patients whose lives depend on them.

To learn more about Calyx's extensive experience in supporting Breakthrough Therapy approvals, contact hello@Calyx.ai.

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