Boudicca Dx

Boudicca DX 2024 Year In Review Newsletter

FIRST AND FOREMOST THANK YOU TO ALL OUR CLIENTS! We thank you for trusting us with your precision medicine consulting needs. It brings us great joy to see your clinical trials start, see your products reach regulatory approval finish lines, see investors invest in your products, see you receive grants to support development, and see your companies get acquired! All of this enables greater patient access to the important precision medicine products that you create! We are truly honored to work with all of you! Most of our clients come to us via referrals so THANK YOU also for being our marketing team and helping us grow! We have supported 114 clients since our existence and would not be here without your support!

🎄 **Boudicca DX has lots to celebrate this 2024 holiday season!** 🎄

- Launched our new website in March thanks to an amazing referral from one of our prior Venture Capital investor clients!
- Became a **WBENC-Certified Women's Business Enterprise** in October, the most widely recognized and respected national certification for women-owned businesses
- Partnered with the **Vanderbilt School of Medicine ASPIRE internship Program** to offer rolling Regulatory Science internships to graduate students & postdoctoral trainees who are interested in learning more about regulatory science
- Our first graduate student intern **Valeria Garcia Lopez** started on December 2nd & is already generating regulatory science tools for clients to use for US and EU clinical trial planning and quickly learning US IDE and EU IVDR regulations
- Promoted **Carlos Murrieta** to CFO and COO to enable our CEO to focus on expanding service offerings to support more clients.

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- Partnered with **32 new clients** this year (biopharma, biotech, a contract research organization, diagnostic companies, consulting firms, investment firms, a digital health developer, and a professional medical organization) and expanded into supporting digital health and digital imaging device product development
- Announced a partnership with **Adial Pharmaceuticals** to support the technical and regulatory strategy for a Companion Diagnostic Genetic Test for AD04, a therapy being developed to treat Alcohol Use Disorder (AUD). This disease affects more than 30 million people in the US alone and causes 3 million deaths worldwide each year.
- Expanded the team adding **6 affiliate consultants** with expertise in Biomarker Operations, Commercialization, Translational Science, Quality Compliance, & MolDx Reimbursement to expand our service offerings and support more clients
- Partnered with **4 strategic alliance partners** to further support clients with global commercialization, regulatory and biostatistics for project-based engagements
- Supported **3 clients** with Final FDA LDT rule readiness planning
- Our Translational Science consulting supported **3 poster abstracts** (co-author):
    - *"An AML targeted Duplex Sequencing assay can detect Measurable Residual Disease (MRD) at a sensitivity better than 0.01% Variant Allele Frequency" with client* ***Twinstrand Bioscience, Transplantation and Cellular Therapy***
    - *"Evaluating the Use of Merlin-YAP Dual-label Immunohistochemistry for Predicting Response to TEAD Inhibitor VT3989" with client* ***Vivace Therapeutics, 36th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics***
    - *"CSF Tumor Cell (CSF-TC) Detection, Quantification and Biomarker assessment helps in clinical management of breast cancer and Non-Small Cell Lung cancer patients having Leptomeningeal Disease (FORESEE Study, NCT05414123)" with prior client* ***Biocept, Society for NeuroOncology***
- Invited to present at **3 conferences/meetings**:
    - *"Navigating the Final FDA Rule on Laboratory Developed Tests regulated as Medical Devices" at the* ***2024 American Pathology Foundation Annual Meeting***
    - *"The Impact of the Latest FDA Regulations on Laboratory Developed Tests (LDTs) for Patient Management" at the* ***American Association of Pharmaceutical Sciences June Open Scientific Discussion***
    - *"Technical and Regulatory Perspectives on Companion Diagnostics" at the* ***2024 American Society of Gene & Cell Therapy Annual Meeting AAV-based Gene Therapies Symposium***
- Published our first white paper on our website: ***"Proposed Framework for Leveraging a Distributed Pan-cancer Profiling IVD as a Companion Diagnostic for Oncology Targeted Molecular Therapies."*** This white paper was written for the precision medicine community to highlight the importance of decentralized

biomarker testing to enable more patients afflicted with cancer to have access to targeted therapies! Reducing the companion diagnostic regulatory burden would free up investment to apply multi-pronged biomarker approaches to therapeutic development and support diagnostic companies developing novel biomarkers and platforms.

- Interviewed in October by **Laboratory Economics,** a monthly business laboratory services industry newsletter, on the importance of working on LDT labeling early to comply with the Final FDA LDT rule: "***Don't Wait to Generate Labeling for Your Lab's LDTs; Early Efforts Can Help Improve Tests, Assist with Later Marketing Submissions***"
- Our CEO was appointed to **3 start-up Scientific Advisory Boards:** Cellens, Proteotype Diagnostics and a Stealth Digital Health technology company
- We also worked behind the scenes:
    - Supporting multiple clients with their FDA breakthrough device designation submissions (BDDs), pre-submissions, investigational device exemptions (IDEs), study risk determinations (SRDs), and marketing submission plans
    - Supporting multiple clients with regulatory strategies for Drug Development Tool Qualification and regulatory documentation review
    - Supporting numerous clinical biomarker development plans, execution and strategies for biomarker rescue missions
    - Implementing Quality Management Systems for emerging companies & laboratories
    - Supporting clients with feasibility studies, analytical, and clinical validation studies
    - Supporting multiple clients navigating EU IVDR regulations for interventional clinical trial assays, including attending multiple EU Scientific Advice meetings to align with EU competent authorities on the assay regulatory requirements, generating and reviewing performance study documentation, and identifying and setting up in-house laboratories in the EU to reduce costs and timelines for Biopharma clinical trials
    - Supporting global companion diagnostic strategies, including Japan PMDA companion diagnostic bridging discussions and China NMPA strategies, working in tandem with clients' consulting partners located in these regions
    - Supporting multiple successful grant applications as an appointed Regulatory Advisor for our clients

An absolutely amazing 2024 with lots of successes for both us and our clients!

Boudicca DX hopes everyone has an amazing holiday season enjoying time with your family, friends, and loved ones! We look forward to continuing to work with our amazing clients and to supporting new clients in 2025!