Boudicca® Dx

2025

Year In Review Newsletter

FIRST AND FOREMOST THANK YOU TO ALL OUR CLIENTS FOR TRUSTING US!

This year brought immense joy to our consulting team helping your targeted therapy global clinical trials start, supporting your clinical biomarker strategies and companion diagnostics for your targeted therapies, supporting your innovative medical device and In Vitro Diagnostic product development, seeing investors invest in your precision medicine products, seeing your therapies become approved by EMA, FDA and MHLW, and seeing your companies become acquired so you can access more patients with life-threatening and debilitating diseases!

Boudicca® DX has LOTS to celebrate this 2025 holiday season!

- Our total number of precision medicine clients supported to date is now **149** (81 Biopharma, 38 Diagnostic/Medical Device/Digital Health/SaMD Developers, 13 Clinical Laboratories, and 17 Investment & Consulting Firms).
- We partnered with **35 new clients** this year, the majority of which came from referrals.
- Our **Boudicca® DX** services trademark was registered with the USPTO for Business consulting services in the field of precision medicine products.
- After supporting EU IVDR compliance from across the Atlantic since May 2022, we opened an EU subsidiary **Boudicca DX Limited** in Ireland in January with the help of the law firm William Fry, who are fabulous! We selected Ireland as it is a global Biopharma and medical devices powerhouse with a large talent pool of highly skilled individuals with compliance experience.
- We opened our EU office in **The Red Church** in Limerick, a renovated Presbyterian church built between 1899-1901 in an Early English Gothic Revival style.

- We hired our first EU hire who works in the Limerick Office, **Courtney Hyland**, an absolute rockstar organizing our EU and US operations and keeping our CEO focused on working on what she loves.
- We renewed our **WBENC-Certified Women's Business Enterprise** certification, the most widely recognized and respected US certification for women-owned businesses.
- We supported two paid graduate student interns from the **Vanderbilt School of Medicine ASPIRE internship Program**.
- We established another paid internship program with the **University College Dublin** **Regulatory Affairs Masters of Science** program and will have our first EU intern this spring.
- We registered with the US federal government and have a **Unique Entity Identifier (UEI) and Commercial and Government Entity (CAGE) code** to be able to offer our precision medicine consulting services to the federal marketplace (eligible for federal contracts, grants, and funds).
- We expanded the global consulting team adding **a PhD-trained, RAC-certified affiliate consultant based in Ireland** with deep expertise in EU MDR and EU IVDR and Notified Body interactions.
- We added a **Board-certified Pathologist** (Anatomic Pathology, Clinical Pathology, and Molecular Pathology) to our consulting team to support clients with the development of immunohistochemistry (IHC) assays, in situ hybridization (ISH) assays, digital pathology products, and molecular diagnostics.
- We added a **Software Quality compliance expert** to our consulting team to support clients with software verification, validation, & cybersecurity.
- Our CEO Dr. Gordon and our Biostatistics consultant Dr. Gillis supported a **digital health technology poster abstract at the International Myeloma Society 22nd Annual Meeting and Exposition**
    - *mQOL, a Text-based Remote Therapeutic Monitoring (RTM) Platform for Symptom (Sx) and Quality of Life (QoL) Tracking in Multiple Myeloma (MM): Interim Results from a Prospective Observational Study*, Blake Morrison, James Berenson, Frank Pezzullo, Pierre Sayad, Randall Noval, **Kelly Gordon, Laura Gillis**, Regina Swift, Victor Tellez, Jamie Cheung, Jon Hall, Aaron Gette, and Alex Wright.
- Our CEO was an invited speaker at **3 meetings**:
    - "*Navigating Companion Diagnostic Regulatory & Operational Challenges*" at the **Industry Pharmacogenomics Working Group** July Meeting.
    - "*Navigating FDA IVD Regulations*" at the **American Pathology Foundation Annual Meeting** in October
    - "*Navigating EU and US Clinical Trial Regulations for Functional Precision Medicine Tests to Bring More Therapeutic Options to Cancer Patients*" at the **Society for Functional Precision Medicine (SfPM)** November meeting.

- We published our **second white paper**: *"PRAGMATIC NAVIGATION OF EU IVDR TO ACCELERATE CLINICAL TRIALS FOR TARGETED PRECISION THERAPIES IN EUROPE."*
- We also worked behind the scenes:
  - Helping clients receive **3 US FDA Breakthrough Device Designations** for their innovative precision medicine tests.
  - Supported **3 Companion Diagnostic Postmarketing Commitments** (from 2-5 years) for FDA-approved targeted therapies.
  - Supported **EMA discussions** on the use of validated local laboratory testing for targeted therapies to ensure greater EU patient access.
  - Supported multiple **US FDA Investigational Device Exemptions, Pre-submissions, Study Risk Determinations (Via Streamlined IND & Q-submissions), De Novos & Modular Premarket Approval Applications.**
  - Supported **US IND filings and EU Clinical Trial Applications** with writing biomarker scientific validity rationale and clinical trial assay documentation.
  - Supported Biopharma with their targeted therapy EU clinical trials and **setting up In-house testing (Article 5(5))** in EU laboratories.
  - Supported **EU central and local laboratories** with In-house testing compliance (Article 5(5)).
  - Supported Biopharma with **performance study applications** for US laboratory-based testing for targeted therapy EU clinical trials.
  - Supported IVD manufacturers & Clinical Research Organizations (CROs) with streamlining analytical and clinical performance protocols & reports and supporting appropriate **fit-for-purpose, stage-specific** studies.
  - Supported global **CDx clinical bridging discussions** with regulators
  - Supported a **Japan PMDA CDx approval** working with Biopharma's consulting partner in Japan.
  - Supported clients with **Quality Management System Implementation & gap analysis** (QMSR, ISO 13485, & ISO 15189).
  - Supported **Biopharma clients with Integrated Device Monitoring.**

An amazing 2025 with lots of successes for us and our clients!

Boudicca® DX hopes everyone has an amazing holiday season enjoying time with family, friends, pets and loved ones! We look forward to continuing to work with our amazing clients and to supporting new clients in 2026!

Thank You

Boudicca® Dx