

Dr. Katie-Louise Dawson's agile and versatile medical professionalism brings a unique and powerful blend of skills developed while serving as medical doctor, public health specialist, and medical monitor across large pharma, biotech, and clinical research organizations. She has served in the capacity of Clinical Development Leader, creating clinical development plans, overseeing clinical studies, providing leadership, and introducing processes that drive efficiencies while ensuring compliance with best practices and regulatory requirements. Dr. Dawson excels at training, developing, mentoring, and positioning new team members, including physicians and scientists, for success.

In particular, Dr. Dawson is noted for:

- **Multiple Clinical and Therapeutic Areas across All Phases of Development:** Instrumental in development of global disease indications in metabolism, hematology/oncology, infectious diseases (including COVID-19 vaccine), biosimilars in rheumatoid arthritis and psoriasis, autoimmune diseases, and dermatology. Rare diseases, including myelodysplastic syndromes, myelofibrosis, idiopathic thrombocytopenic purpura (ITP) and alopecia areata.
- **Project Leadership and Collaboration:** Partnered with commercial, medical science liaisons, medical information, and health outcomes teams on the launch of three eltrombopag indications (ITP, HCV-associated thrombocytopenia, and cytopenias associated with aplastic anemia). Project lead for the GSK Global Compassionate Use Program enabling patients with minimal treatment options to benefit. Supported global investigator sponsored studies.
- **Liaison with Regulatory:** Contributed to orphan drug applications, summaries of clinical efficacy and safety for investigational new drug application and end of phase 2 meetings. Author of 510(k) submissions and clinical evaluation reports for medical devices. Negotiated Risk Evaluation Mitigation Strategy (REMS) and US Prescribing Information. Contributed to switch of prescription (Rx) products to over the counter (OTC).
- **Functional Leadership | SOP Liaison:** Matured the medical monitoring function for CRO, authoring SOPs for Medical and Scientific Affairs, development of informed consent, reference safety information, managing protocol deviations, and creating medical monitoring manual and onboarding processes. Harmonized SOPs during a two-year transition period resulting from merger of two CROs. Introduced new SOPs, protocol writing and medical data review processes.
- **Medical Monitor:** Enabled treatment for patient populations where there was significant unmet medical need. Lead Medical Monitor to multiple global studies including phase 3 COVID-19 vaccine program.
- **Liaison with Business Development:** Influential member of team achieving a high win rate in CRO bid defenses for all study phases and securing substantial new business. Significant experience in due diligence developed while evaluating multiple new opportunities and licensing deals for additional revenue at GSK Consumer Health.
- **Medical Affairs:** served as Medical Director providing medical review of promotional materials in several therapy areas.
- **Project Leader and Lead Physician:** Led a tri-partner Strategic Alliance, serving as clinical development lead and medical monitor for post-marketing commitment studies. Negotiated updates to US Prescribing information with FDA for multiple post-marketing safety issues.