



AyurDatta: Our Capabilities & Value Proposition

Our Value Proposition: Fusing Clinical Wisdom with AI-Powered Execution

AyurDatta offers a new, integrated partnership model that eliminates the friction between brilliant science and flawless execution. We combine the deep, physician-led clinical and regulatory expertise of Dr. Ashok Srivastava with the proven, AI-powered operational engine architected by Elias Tharakan. The result is an accelerated, de-risked path to approval for our partners.

Core Services & Expertise

Clinical Trial Leadership & Execution

- **Strategy & Design:** Physician-led protocol design for all phases, from Phase 1 First-in-Human (3+3 design, dose escalation/de-escalation, DLT/MTD/MAD) to global Phase 3 registration studies.
- **Therapeutic Focus:** Deep expertise in **Solid Tumors** and **Hematologic Malignancies**.
- **Advanced Modalities:** Specialized leadership for **CAR-T**, **Antibody-Drug Conjugate (ADC)**, **Oncolytic Virus**, and **Chemo-immunotherapy** programs.

Medical Safety & Pharmacovigilance

- **Case Management:** Comprehensive case classification and processing (MedDRA/WHO-Drug coding).
- **Medical Monitoring:** 24/7 physician-led oversight and expert DSMB participation.
- **Narrative Writing:** High-quality, submission-ready safety narratives.

Safety Data Analysis & Reporting

- **Aggregate Reporting:** Expert authoring of DSURs, PSURs, and PADERs.
- **Signal Detection & Risk Management:** Proactive signal detection and strategic risk management plan development.
- **Systems Management:** Full support for ARGUS safety database management.



Regulatory Affairs & Submission Support

- **Global Agency Interaction:** Preparation for and participation in meetings with the FDA, EMA, and other global health authorities.
- **Submission Expertise:** End-to-end support for **IND, NDA, sNDA, ANDA (505(b)(2)),** and **BLA** submissions.
- **Compliance Reporting:** Management of labeling, CIOMS, and MedWatch reporting.

Deep Therapeutic Area Experience

Cell & Gene Therapies:

- Autologous & Allogeneic CAR-T Immunotherapy for Lymphoma, Leukemia, and Melanoma.
- Leadership experience in R/R CD19+ B-ALL (adult/pediatric), AML (FLT3), CLL, CML, Follicular Lymphoma, Mantle Cell Lymphoma, DLBCL, and Multiple Myeloma.

Solid Tumors:

- Extensive program experience in Glioblastoma, Breast Cancer (PI3K α , CDK4/6 inhibitors in HER2-, HR+/HER2-, TNBC), Bladder Cancer (NMIBC), GIST, NSCLC, Colorectal, and Pancreatic cancers.
- Expertise in rare malignancies including Sarcoma and Ovarian Cancers with MAPK, KRAS, NRAS, and BRAF mutations.

Next Steps

We would be delighted to schedule a confidential, complimentary discussion to explore how our integrated model can bring greater efficiency and strategic value to your clinical programs.

Contact Us:

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