**Kentre L. Horton**

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**Career Profile**

A background that includes clinical trials, laboratory science, and regulatory compliance, with a practical, detail-oriented approach to supporting complex research operations. Worked across clinical trial phases, managing site communications, essential documentation, and data review for large-scale studies in hepatology. Supported site operations for up to 30 trial locations, collaborated closely with labs and vendors, and used tools like Medidata CTMS, EDC, and Tableau to track and visualize progress. Earlier experiences in pharmaceutical manufacturing labs sharpened understanding of GMP compliance and data integrity. Along the way, mentored peers, earned multiple recognition awards, and built a solid reputation for reliability and follow-through, whether tracking data, solving problems, or supporting a new system rollout.

**Technical Skills**

**Regulatory & Compliance Knowledge:** cGMP | GMP | PSO | Advarra Central IRB  
**Clinical Trial & Lab Systems:** Phlex-E View Trial Master File (TMF) | Medidata CTMS & RTSM | Medidata EDC | Flex Advantage (IRT) | Cerba Central Lab | Medpace Central Lab | Perspectum Central Imaging  
**Electronic Documentation & Workflow Tools:** Electronic Lab Notebook (ELN) | Box | Veeva Vault EDMS | DocuSign | Workday  
**Data Analysis & Visualization:** Tableau Dashboards  
**Therapeutic Area Expertise:** Hepatology

**Microsoft Office Suite**: Word, Excel, PowerPoint, OneNote, Teams

**Professional Work Experience**

**ICON PLC,** Raleigh, NC(Formerly PRA Health Sciences) 06/2021 – 03/2025

A leading healthcare intelligence and clinical research organization known for providing outsourced development and commercialization services to pharmaceutical, biotechnology, medical device, and government and public health organizations. ​

**Clinical Trial SMA 1 – Remote** **(position impacted due to larger RIF)** 08/2022 – 03/2025

**Clinical Trial Site Management Associate – Charlottesville, VA** 06/2021 – 08/2022

Reported to the Site Manager (SM) and the Clinical Trial Managers (CTM). Acted as primary site contact/liaison for study and site management issues. Completed essential document collection and review throughout study lifecycle, organized and maintained site clinical trial master file (TMF) documents. Performed data review, inclusive of site-level data assessment, query resolution, facilitated database closure and freezing procedures as per study plans. Performed all tasks according to applicable guidelines (e.g., ICH-GCP), company and sponsor SOPs, project plans, study-specific processes, and local regulatory requirements.

* Received multiple INSPIRE awards throughout the years for collaboration and agility.
* Became an SMA Mentor after 1st year with the company and mentored multiple SMAs.
* Consistently met or exceeded key performance standards, including quality and deadlines.
* Nominated for – will provide this info (still working to obtain)

**Study Experience:**

Akero-US-001-0105 | Akero-US-001-0106 | Akero-US-001-0107 – Managing up to 18 sites.

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of XXX in Subjects with Non-Invasively Diagnosed Nonalcoholic Stethohepatitis (NASH) Metabolic Dysfunction-Associated Steatohepatitis (MASH) and Nonalcoholic Fatty Liver Disease (NAFLD) Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD).

Bio89-100-122 – Managing up to 30 sites

A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of XXX in Subjects with Biopsy-Confirmed Nonalcoholic Steatohepatitis (NASH).

**Alcam**i,Wilmington, NC 06/2020 – 05/2021

A contract development and manufacturing organization (CDMO) with over 45 years of experience, offering integrated services including drug product manufacturing, analytical development, and cGMP storage to pharmaceutical and biotech companies.

**Assistant Scientist II**

Reported to the Analytical Testing Shift Supervisor. Performed analytical routine and non-routine testing in support of pharmaceutical product development or pharmaceutical manufacturing. Assisted with method development/method validation projects. Maintained working knowledge of instrumentation, equipment, and scientific methodologies necessary to perform assigned tasks.

* Ensured timely completion and compliance with cGMP and all other relevant company training requirements.
* Successfully aided analytical testing department out of 6-month work backlog within 8 months of starting position.

**Quality Chemical Laboratories**, Wilmington, NC 08/2018 – 05/2020

A contract development and manufacturing organization, specializing in analytical development, formulation, and GMP manufacturing services for the pharmaceutical and biotech industries.

**Analytical Chemist**

Reported to the Laboratory Supervisor. Performed established quality control test methods, including visual appearance, moisture, titrimetric assays, colorimetric identifications, and pH tests. Documented laboratory testing with strict adherence to QCL SOPs and all regulatory standards. Staged projects in tracking software daily. Maintained strict client confidentiality and adherence to safety standards. Performed testing with multiple pharmacopeia (USP, EP, JP, JPE, JPC, FCC, ACS). Recognized aberrant data and worked with laboratory management to investigate it.

* Maintained training requirements on all necessary disciplines: Wet Chemistry | Gravimetric | pH | Elemental Karl Fischer Titrations | FT-IR | Conductivity | Thin-Layer Chromatography (TLC) | UV-Vis.

**Northern Southeast Regional Aquaculture Association (NSRAA)**, Sitka, AK 01/2017 – 10/2017

A nonprofit that enhances salmon stocks in Southeast Alaska to support commercial, sport, and subsistence fisheries.

**Hatchery Technician (one-season contract)**

Helped to rear, pond, raise, release, and spawn chum, chinook, and coho salmon. Fed, raised, and released over 30 million chum salmon. Sampled fish populations, calculated average size in a population, and the amount to feed, based on growth rates. Learned Partnered with others to build, set up, operate, and break down the hatchery’s green lake project, which housed approximately 1 million fish in 10 net pens.

**Education**

**Bachelor of Science, Marine Biology**, (Minor: Sociology), University of North Carolina Wilmington, Wilmington, NC

* **UNCW Division II Men’s Rugby Club** | Top 10 in USA College 15’s DII National Ranking 2014 and 2015 season
* **Directed Individual Study (DIS)** – UNCW Center for Marine Science – Maintained a 265-gallon aquaria system for marine research by collecting and caring for ascidian and sponge species, supporting experiments on sponge growth and nitrogen ratios. Created the first user manual to ensure long-term system operation.
* **Multiple Internships** – North Carolina Aquarium at Fort Fisher & UNCW Aquaculture Facility – Completed over 450 hours of hands-on internship experience, gaining skills in tank maintenance, animal care, water testing, record keeping, and field collection. Supported staff with feeding, cleaning, and maintaining life support systems across multiple aquatic environments.

**Volunteerism**

**Volunteer** – NC Coastal Federation at Wrightsville Beach – Set up and maintained aquaria systems used for public education on coastal habitats. Trained others on system care and the connection between aquarium science and natural marine ecosystems.