



ELEMENT BOULDER

NAVIGATE COMPLEX VALIDATION REQUIREMENTS WITH CONFIDENCE



ABOUT ELEMENT BOULDER

Element Boulder is a clinical validation and research laboratory that conducts IRB-approved protocols to evaluate accuracy, usability, and real-world physiological performance for connected and wearable health technologies.

The Boulder Quality Management System is built around ISO/IEC 17025:2017, ensuring technical competence and rigorous data integrity throughout your testing protocol.

WHY PARTNER WITH ELEMENT BOULDER

- Overcome regulatory challenges that threaten approval and delay market entry
- Access our extensive participant database with diverse physiologies
- Ensure quality with on-site Chief Medical Officer oversight for all studies
- Streamline IRB approvals with our established Advarra IRB relationship
- Benefit from end-to-end study management, from protocol to FDA-ready reports

KEY SERVICES

- SpO2/Hypoxia Studies
- Human Factors and Usability Testing
- Method Development & Validation
- Regulatory Documentation Support
- Respiratory Rate Monitor Validation
- Heart Rate Monitor Device Validation
- Sleep Studies
- Temperature Studies
- Blood Pressure Monitoring Validation (Invasive and Noninvasive Testing)

SUPPORT AT EVERY STAGE

Our team of qualified medical technicians, engineers, and clinical research professionals are here to support your program from protocol development through execution and final reporting.

EARLY DEVELOPMENT

- Support calibration with non-blood studies
- Perform preliminary verification testing
- Design custom test protocols

CLINICAL & REGULATORY

- Conduct ISO-compliant validation studies
- Generate FDA-ready validation reports
- Meet stringent regulatory requirements

COMMERCIAL

- Support product modification testing
- Verify performance after device changes
- Document ongoing safety and efficacy

ELEMENT BOULDER

BLOOD PRESSURE MONITORING

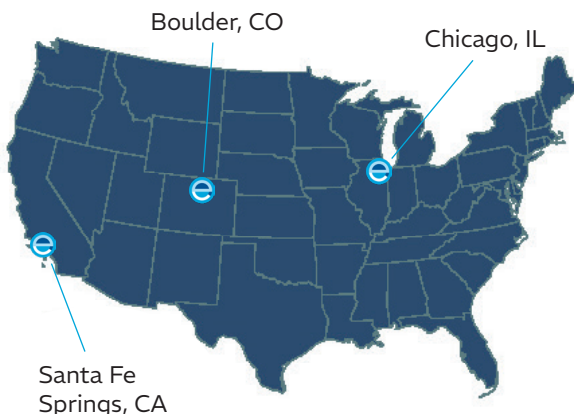
- **ISO 81060-2 Non-invasive Validation** - Comprehensive accuracy validation
- **Same Arm Sequential/Opposite Arm Methods** - Multiple validation approaches
- **Digital Manometer Technology** - Precise measurement capabilities
- **NIST-Traceable Equipment** - Ensuring measurement accuracy
- **IEEE 1708 Wearable Device Testing** - Specialized protocols for cuffless technologies
- **Diverse Subject Demographics** - Representation across age, BMI, and skin tones
- **FDA-Ready Documentation** - Complete reports supporting regulatory submissions

HUMAN FACTORS & USABILITY

- **Formative Usability Studies** - Early-stage user interaction evaluation
- **Summative Validation** - FDA-compliant user interface assessment
- **Home Use Testing** - Real-world environment evaluation
- **Risk Identification** - Potential use errors and mitigation strategies
- **User Interface Optimization** - Evidence-based design improvements
- **Regulatory Documentation** - Complete HFE/UE reports for submission

DIVERSE PARTICIPANTS

Our satellite locations in Chicago, IL and Santa Fe Springs, CA give us access to a diverse pool of clinical trial participants.



SPO2 / HYPOXIA STUDIES

- **ISO 80601-2-Compliant Testing** - Comprehensive validation for regulatory submission
- **Transfer Standard Methodology** - Efficient non-blood calibration development
- **Blood Validation Studies** - Gold-standard arterial blood comparison
- **Monk Skin Tone Scale Integration** - Complete demographic representation
- **Customized Protocol Development** - Tailored approaches for unique device challenges
- **Deep Subject Database** - Access to diverse physiologies and skin tones
- **Comprehensive Analysis** - Detailed accuracy and performance reporting
- **FDA-Ready Documentation** - Complete reports supporting regulatory submissions

SPECIALIZED MEDICAL DEVICE TESTING

- **Respiratory Rate Validation** - Specialized protocols for breathing monitoring
- **Temperature Monitoring Validation** - Precision assessment across measurement ranges
- **Sleep Monitoring Studies** - Specialized evaluation for sleep technology
- **Motion/Activity Monitoring** - Performance validation during movement
- **Low Perfusion Testing** - Evaluation under challenging conditions
- **EKG/Heart Rate Monitoring** - Comprehensive cardiac signal validation
- **Algorithm Development Support** - Data generation for improved performance
- **Fetal Heart Rate Monitoring** - Specialized validation for prenatal and labor settings
- **Pediatric Studies** - Population-specific protocols for children under 18 years old

LEARN MORE

