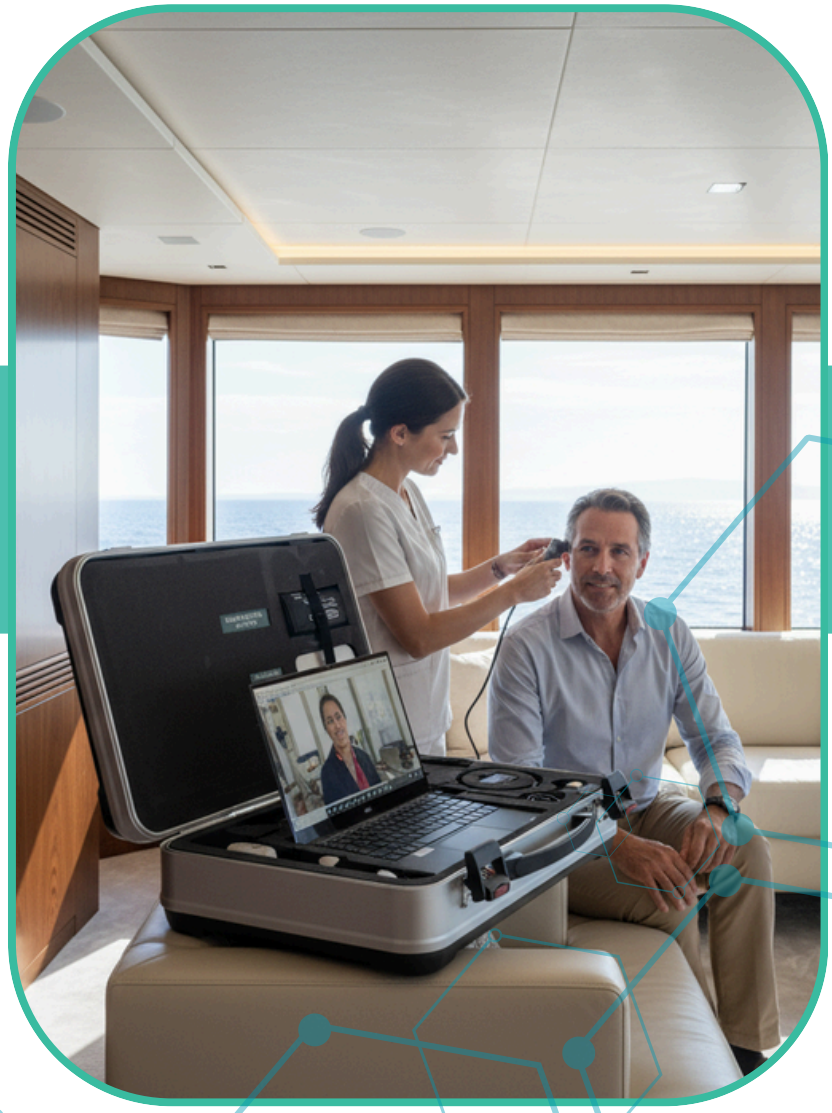
GAL3N

Remote Healthcare

Clinical Research White Paper



Clinical research is evolving faster than ever, and today's sites, CROs, and investigators are under increasing pressure to deliver faster enrollment, broader reach, and higher-quality data–without sacrificing compliance or patient safety. As decentralized and hybrid trial models become the new industry standard, traditional site-bound workflows can no longer keep up. Gal3n bridges this gap by enabling complete remote physical examinations, real-time PI oversight, and FDA-aligned digital data capture from virtually any location. This technology empowers research teams to expand capacity, improve retention, and deliver audit-ready results while offering participants a more accessible, patient-centered experience.

Equipment

Otoscope

Stethoscope

Dermatocoscope

Gal3n is a telehealth software platform that enables clinicians to perform real-time remote physical exams using connected FDA-cleared medical devices. It provides secure video sessions, remote device control, and automatic capture of diagnostic data such as images, audio, and vitals. The system supports HIPAA and 21 CFR Part 11 requirements and integrates with eSource/EDC workflows. Gal3n is used to extend clinical oversight across multiple locations, including sites, satellite centers, and home visits.

PI Flexibility Reimagined

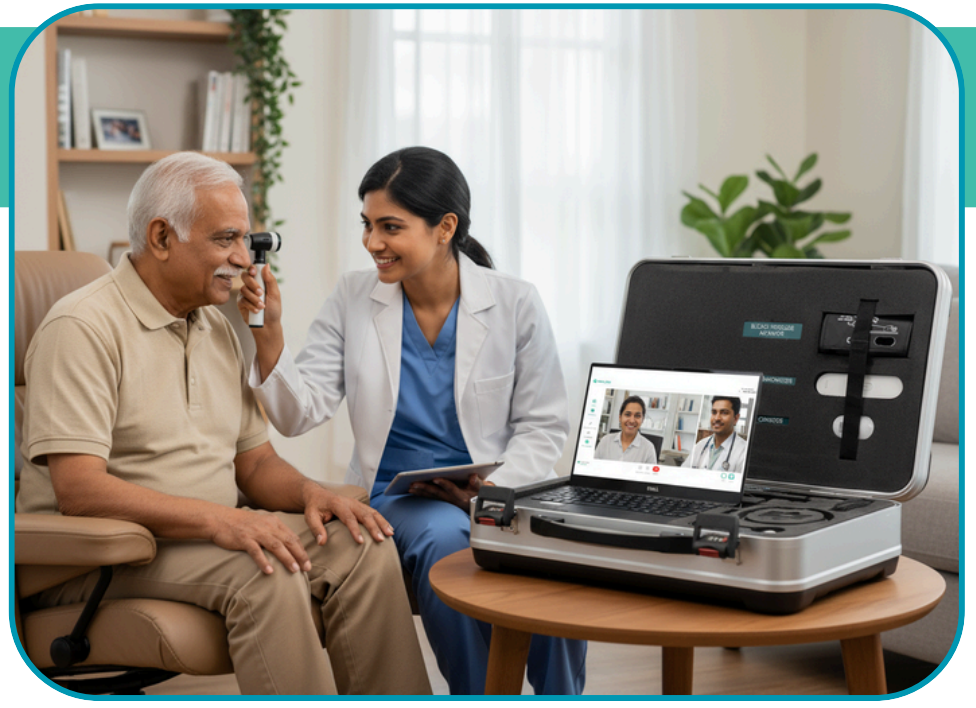
Principal Investigators no longer need to travel between sites or rearrange full schedules just to complete required visits. With Gal3n, PIs can connect instantly from anywhere to observe exams, interact with participants, and guide study teams in real time.

What This Unlocks:

- **Optimized Workflows:** PIs manage multiple studies without losing time to travel.
- **Expanded Capacity:** One PI can confidently oversee more subjects and more sites.
- **Nationwide Access:** Sites can contract PIs and specialists from any region, expanding therapeutic coverage.
- **Higher Retention:** Remote oversight eliminates delays that typically cause missed visits or dropouts.

Gal3n turns PI oversight into a scalable, high-efficiency model that supports rapid enrollment and stronger sponsor performance.

At-Home Remote Visits & Nationwide Recruitment



Gal3n enables fully supported at-home trial visits through FDA-cleared diagnostic peripherals and high-resolution, real-time telehealth. Instead of asking participants to come to the site, the site comes to them.

Key Advantages:

- **Recruit From Anywhere:**Enroll participants across the country while keeping oversight centralized and audit-ready.
- **Reach Rural & Underserved Populations:**Allow patients in areas with limited research access to participate without long travel.
- **Include Mobility-Limited Participants :**Remove barriers that prevent patients with disabilities, chronic illnesses, or transportation challenges from enrolling.
- **Expand Capacity Without Expanding Space:**Shift routine visits outside the clinic and manage more patients simultaneously.
- **Reduce Burden → Increase Retention:**Less travel, fewer logistical hurdles, and more flexibility mean higher adherence and lower dropout rates.
- **Accelerate Study Timelines:**Faster recruitment + fewer missed visits = quicker completion of endpoints.

Impact for Sites:

- **More trials without added overhead**
- **Better diversity and inclusion**
- **Stronger sponsor relationships**
- **Competitive advantage in study selection**

Regulatory Alignment: FDA-Ready Digital Health Technologies

Today, regulatory bodies demand validated digital tools, transparent audit trails, and strong oversight—even when trials are decentralized. Gal3n was built to meet and exceed these standards.

How Gal3n Delivers Compliance:

- **FDA-Cleared Diagnostic Devices:** Digital stethoscopes, otoscopes, dermatoscopes, vitals monitors, and HD cameras ensure accurate, validated data.
- **Audit-Ready Documentation:** Every video, image, diagnostic reading, and metadata point is automatically logged to withstand FDA, GCP, ICH, and IRB inspection.
- **Secure, Traceable Data Integrity:**HIPAA-compliant, 21 CFR Part 11-ready infrastructure ensures data is encrypted, durable, and fully traceable.
- **Remote PI Oversight Built for Regulators:** Gal3n aligns with FDA's DHT guidance—supporting remote assessments without compromising quality.

Research Sites

A mid-size site struggling with PI availability, visit delays, and dropouts implemented G-Carts onsite and G-Pods in remote areas.

Within one quarter:

- Visit delays dropped 60%
- Enrollment expanded into rural regions
- Sponsor satisfaction improved through verifiable digital audit trails
- The site became a preferred partner for decentralized and hybrid trials

Case Study: ClearView Research

A decentralized asthma trial risked falling behind due to missed visits and PI scheduling challenges. **With Gal3n:**

- Dr. Bennett conducted full remote lung and vitals exams
- Data flowed directly into 21 CFR Part 11-compliant eSource
- Rural recruitment increased
- A participant who previously missed multiple visits completed every remaining appointment

Gal3n turned a stalled study into an efficient, patient-centric operation.

CROs

A CRO managing several decentralized trials standardized all sites on **Gal3n** to unify PI oversight and improve monitoring quality.

Within six months:

- Protocol deviations decreased 40%
- Required visits were completed 60% faster
- Monitoring costs dropped due to fewer onsite visits
- Sponsors noted higher data quality and faster query resolution

Case Study: Apex Clinical Research CRO

Apex faced delays, fragmented data, and limited investigator availability. **After deploying G-Carts and G-Pods:**

- PIs performed real-time remote exams with FDA-cleared peripherals
- All data synced automatically to eSource for sponsor review
- Recruitment expanded into remote regions
- Study timelines accelerated across all programs

Gal3n helped Apex transform complex decentralized trials into streamlined, compliant operations.