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Driving Innovation: The Role of Cross-Functional Collaboration

Advancing renal care technologies through multidisciplinary teams

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Why collaboration is the innovation multiplier

Today's agenda:
- Frameworks
- Case studies
- Challenges
- Trends

Renal care demands precision, safety, and speed of learning

No single function owns patient outcomes—teams do

Cross-functional ways of working reduce risk and time-to-impact

Executive summary | Key highlights

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How multidisciplinary teams accelerate safe innovation

Collaboration Fundamentals

What “cross-functional” really means

Why it matters	How we do it
End-to-end ownership: from needs discovery to post-market surveillance	Map the product lifecycle and assign clear accountabilities
Integrated safety and human factors thinking from day one	Stand up a core team (R&D, Medical, Design, QA/RA, Manufacturing, Market Access)
Closed-loop learning: medical insights → design decisions → field feedback	Adopt shared artifacts: problem statements, risk registers, usability goals

Collaboration across the device lifecycle

Phase		Development	Verification/ Validation	
R&D	Feasibility & architecture	Design controls & traceability	Bench & reliability testing	CAPA inputs & enhancements
Product Design	User research, HFE plans	Prototyping & formative studies	Summative usability	Labeling & training iteration
Medical	Unmet need & endpoints	Protocol design & IRB alignment	Medical investigations	Real-world evidence & PMS
QA/RA	Reg strategy & classification	QMS, risk mgmt (ISO 14971)	Design verification / validation	Complaints, UDI, vigilance

Rituals that keep teams in sync

- Weekly integrated risk review (design, medical, manufacturing)
- Evidence backlog groomed with medical + R&D co-ownership
- HFE checkpoints at milestone gates (formative → summative)
- Pre-sub letter drafting as a cross-functional workshop
- Post-market signal triage with design action items within 48–72h

Measuring collaboration | Leading & lagging indicators

Leading indicators	Lagging indicators
Leading: time from medical feedback → design change proposal	Lagging: design-related complaints per 1,000 treatments
Leading: percentage of Change Requests with cross-functional reviewers	Lagging: verification defect escape rate
Leading: HFE defects found during formative (not summative)	Lagging: time-to-approval and time-to-first-patient

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Cross-functional initiatives in renal devices

Case study #1 — Portfolio integration

Fresenius Medical Care

- **Context**: Integrating an acquired home hemodialysis platform into a global portfolio
  - **R&D + Medical**: therapy parameter harmonization and safety cases
  - **Design + HFE**: home user training pathways and UI coherence
  - **RA/QA**: design history file alignment and global submissions strategy
- **Outcome**: Streamlined training burden and aligned risk controls across markets

Case study #2 — Digital companion & connectivity

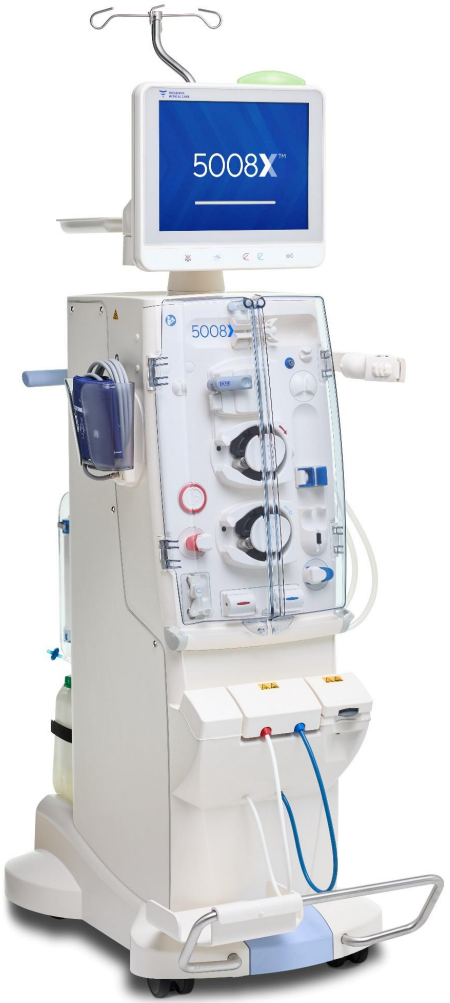
Fresenius Medical Care

- **Context**: Extending device value via connected data and patient support tools
  - **R&D + Digital**: secure telemetry and data pipelines for analytics
  - **Medical**: protocolized remote monitoring and escalation pathways
  - **Design**: patient-facing UX for adherence and self-management
- **Outcome**: Earlier signal detection and improved patient engagement metrics

Case study #3 — Iterating a dialysis delivery system

Fresenius Medical Care

- **Context**: Next-gen updates to a widely deployed in-center dialysis system
  - **Product Design**: usability improvements validated with clinicians
  - **R&D**: modular subsystems enabling faster verification cycles
  - **Clinical/Medical Affairs**: real-world data informing alarm thresholds
- **Outcome**: Reduced alarm fatigue and improved treatment workflow efficiency



Case Study – The 5008X Hemodialysis System

- Cross-functional development involving R&D, Medical, and Design teams
  - AutoFlow, Online Clearance, & AutoSub Plus features developed through iterative feedback cycles
  - Human Factors Engineering (HFE) validation improving ease of use
  - Collaboration on sustainability—reduced energy and water consumption
- Outcome: Safer, more efficient, and sustainable therapy delivery

Emerging Technology – Continuous Kidney Replacement Therapies (CKRT)

- R&D–Medical collaboration on next-generation compact systems for acute kidney injury (AKI)
  - Integration of AI-supported fluid management and predictive analytics
  - Co-design with ICU clinicians to improve workflow and monitoring accuracy
  - Iterative feedback informing software refinements and usability testing
- Outcome: Enhanced safety and precision in critical care renal therapies

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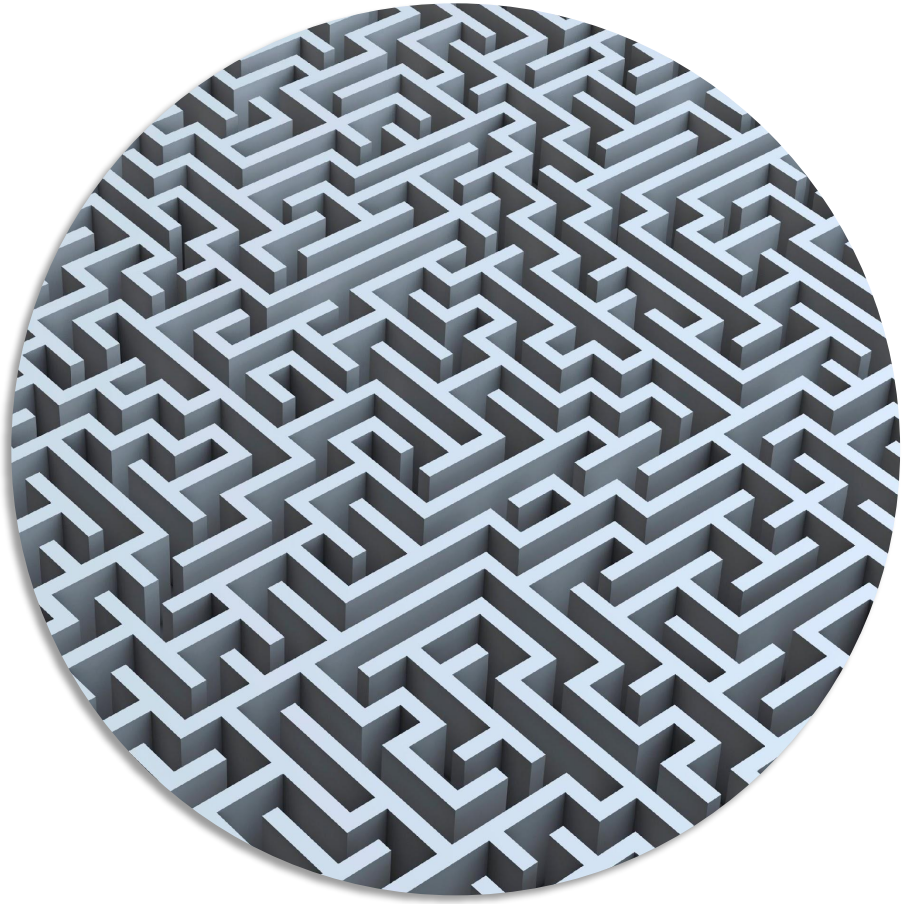
Building a culture where collaboration thrives

Common pitfalls that derail collaboration

- Late Medical involvement leading to rework
- Siloed risk management artifacts across functions
- Underpowered HFE investment until too late
- Ambiguous ownership for post-market learnings
- Tool sprawl and version confusion



Solutions playbook

Why it matters	How we do it
Embed medical & HFE from discovery; budget their time in the plan	Quarterly cross-functional pre-mortems on top risks
Define a single source of truth for risk and requirements	Joint authorship for pre-subs and responses
Create a decision log accessible to all functions	Rotate leads for sprint demos to broaden context
Establish design authority and escalation pathways	Consolidate tools; automate traceability where possible

Lightweight governance (RACI Example)

Workstream	Responsible	Accountable	Consulted	Informed
Clinical evidence strategy	Medical	Medical Affairs	R&D, RA	Design, Ops
Human factors & usability	Design/HFE	Product	Medical, QA	R&D
Design controls & traceability	R&D	QA/RA	Design, Medical	Ops
Post-market surveillance	QA/RA	Medical Affairs	R&D, Ops	Design

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What’s next & why it matters

Trends shaping renal care and patient outcomes

Why it matters	How we do it
Home-first therapies & portable systems	Implications: adherence, safety, reduced burden on clinicians
Sensor-rich devices enabling predictive maintenance and dose personalization	Data governance: privacy-by-design and cybersecurity by default
Closed-loop fluid management and AI-supported decision aids	Evidence: in silico mathematical models; RWE pipelines integrated with clinical investigations
Complimentary modalities in extracorporeal circuits and novel dialyzer materials	Equity: usability for diverse patient populations
Vascular access monitoring via wearables/ultrasound adjuncts	

Leveraging digital tools to collaborate more effectively

- Shared requirements & risk systems with automated traceability
- Electronic design controls integrated with issue tracking
- Remote formative studies (telepresence, remote sims) for HFE
- Secure data platforms for real-world evidence and vigilance
- Dashboards for leading/lagging metrics across functions

Practical toolkit you can reuse

- One-page problem statement and success criteria
- Evidence backlog template (design + clinical)
- Risk register with cross-functional owners
- Decision log and design history snapshots
- Pre-sub checklist and response tracker

Synthesis: Lessons from Fresenius Medical Care Initiatives

- AI, data, and medical integration are reshaping renal device innovation
- Cross-functional feedback loops accelerate design and improve outcomes
- Digital health ecosystems extend device value beyond the clinic
- Collaborative culture enables scalable, patient-centric innovations

Thank you

Driving innovation requires all of us.

Questions & discussion

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Addendum – work in progress

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Pick one area to explore with the audience (5 minutes)

Interactive prompts (choose one)

How do you operationalize real-world evidence into sprint planning?

What metrics most changed behavior on your team?

Where did human factors findings most surprise you—and how did you respond?

Your first 90 days | Action plan

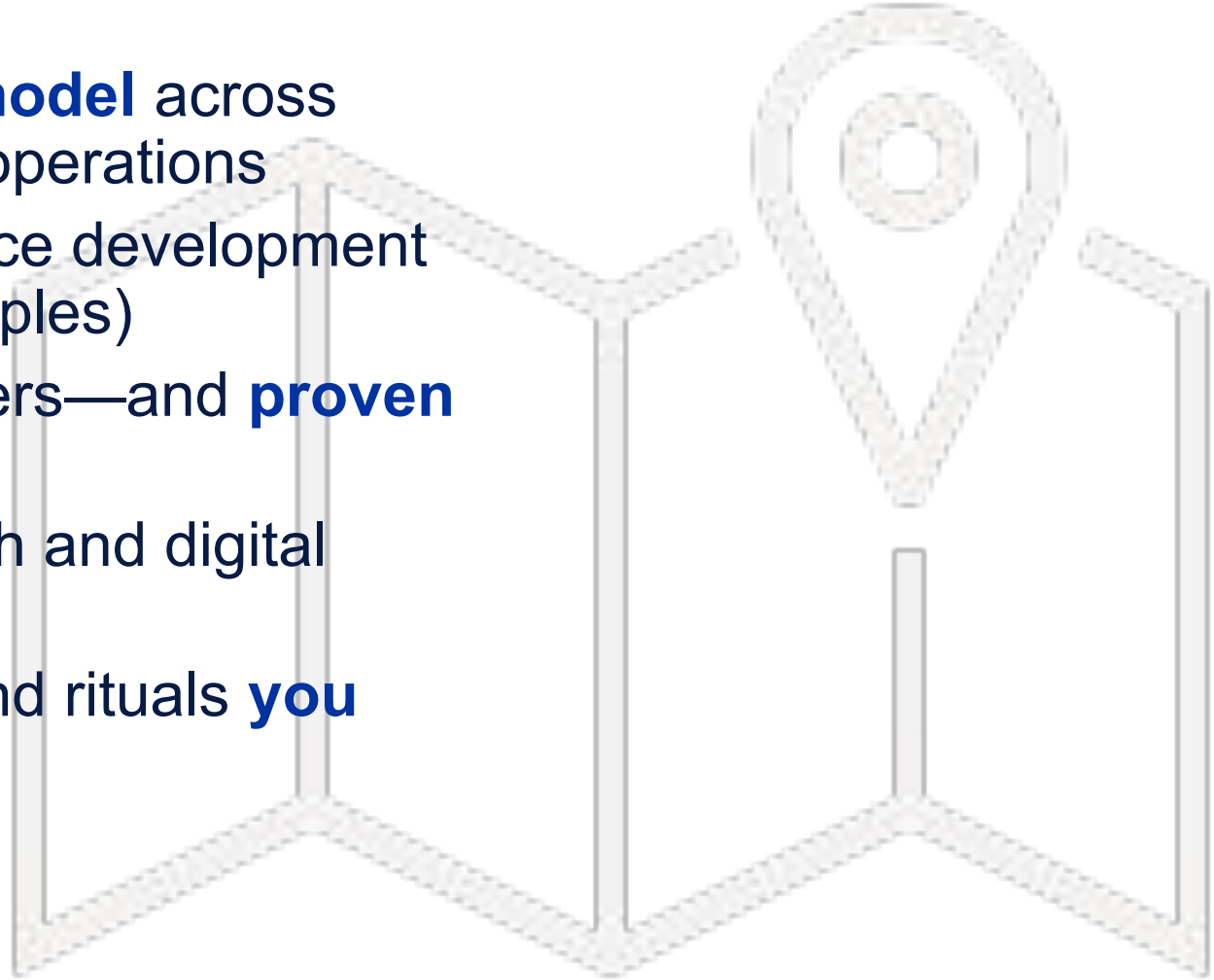
Why it matters	How we do it
Map lifecycle and gaps; define owners for evidence & risk	Instrument 3 leading indicators and 2 lagging ones
Pilot a weekly integrated risk review with 1 product team	Schedule a pre-mortem + post-mortem cadence
Stand up a shared artifact hub; migrate high-value docs	Plan one formative HFE study earlier than usual

References & disclaimers

- Case-study slides are templates—replace with approved Fresenius Medical Care details
- Ensure all performance/claims are supported by cleared labeling and published evidence
- Views are presenter’s own; not investment or regulatory advice

Session objectives & takeaways (30 minutes)

- Define a **practical collaboration model** across R&D, design, clinical, QA/RA, and operations
- Analyze **case studies** in renal device development (with Fresenius Medical Care examples)
- Identify cultural and structural barriers—and **proven solutions**
- Scan **emerging trends** in renal tech and digital health collaboration
- Leave with a playbook of metrics and rituals **you can adopt Monday**



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Integrating AI, remote monitoring, and next-gen therapies

Case Study – AI-Driven Predictive Analytics in Dialysis

- Cross-functional collaboration between R&D, Data Science, and Medical teams
  - Machine learning models predicting intradialytic hypotension and optimizing ultrafiltration
  - Clinical validation and integration into dialysis software systems
  - Feedback loops between data teams and nephrologists for continuous refinement
- Outcome: Enhanced patient stability, reduced unplanned interventions, and data-driven insights for therapy personalization

Case Study – Remote Patient Monitoring (RPM) Ecosystem

- Joint initiative across R&D, IT, Medical, and Care Management functions
  - Connected home dialysis systems securely transmitting treatment data
  - Predictive alerts empowering early interventions by care teams
  - Collaborative development ensuring interoperability with clinical systems
- Outcome: Improved adherence, proactive care, and real-time oversight of home therapies

Case Study – Home Hemodialysis & Peritoneal Dialysis Programs

- Integrated approach combining patient-centered design, telemonitoring, and training
  - UX and education teams simplifying setup and alarm handling for home users
  - Medical and technical collaboration ensuring secure remote data review
  - Care pathway optimization informed by patient feedback
- Outcome: Greater independence for patients and improved adherence through intuitive systems

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