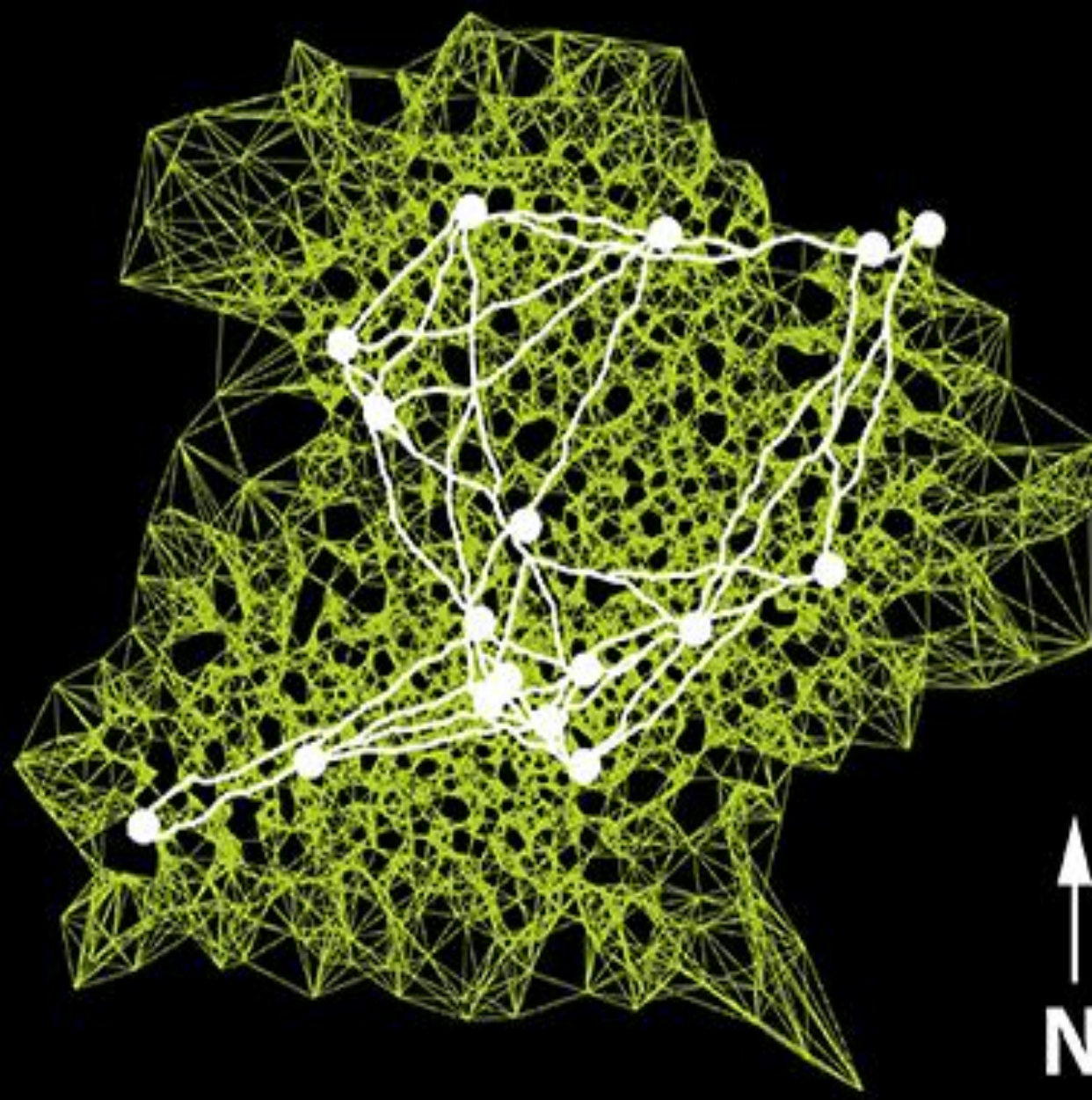
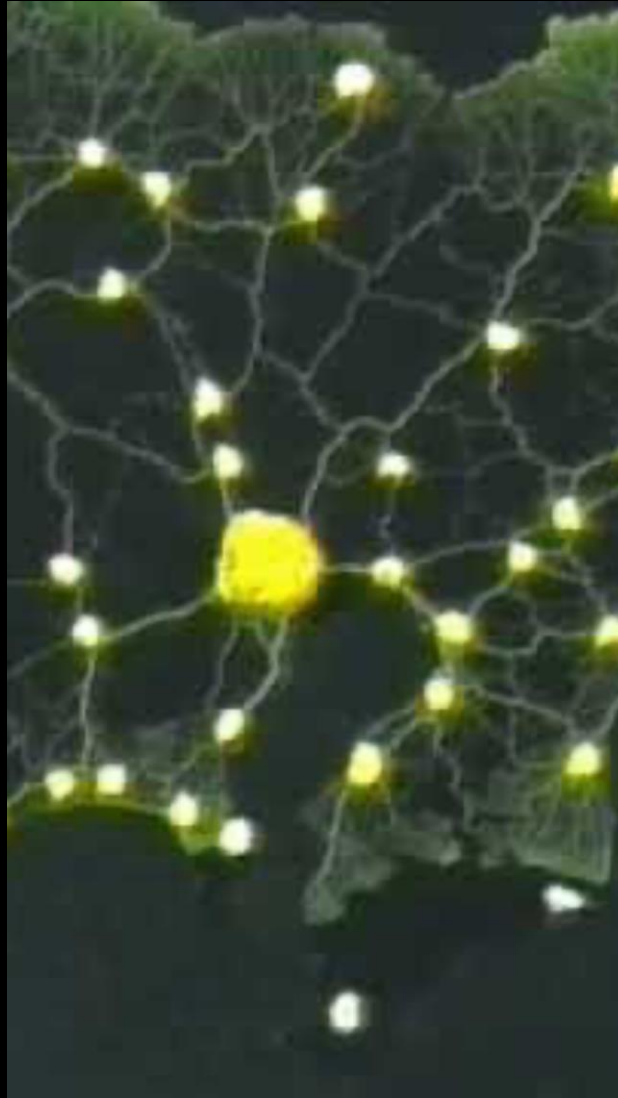




OPENING — Play video as audience enters. Begin voiceover when room settles.



Tero et al. 'Rules for Biologically Inspired Adaptive Network Design.' Science, 327(5964), 2010.



Annual

**Advances and Innovations in Endoscopic Oncology
and Multidisciplinary Gastrointestinal Cancer Care**

What Can MedTech Learn from Pharma?

The Business Perspective

Brad Maruca, MBA, MS

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Deloitte



Disclosure

- This is a Non-CME Accredited session.



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Change in Medtech isn't viral, it's bacterial

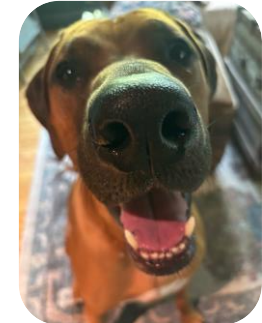
99

Introduction

- 26 years in Medtech
- 20 years active implantables (class III): neuromodulation at Abbott (formerly St. Jude Medical)
- Core TAs: chronic pain and movement disorders e.g., PD, ET, and dystonia
- Emerging TAs: depression, PVD, and DPN
- Functional leadership in commercial and clinical e.g., marketing, product management, KOL engagement, medical education and clinical research strategy
- Proficient at dealing with cantankerous doctors and clients...years of experience

Background and Interests/Professional Affiliations

- Undergraduate degree in Biology from FSU, MBA from SMU and MS in Financial Economics from Purdue
- Love to learn by hate to be taught
- Married 30 years to my college sweetheart, Niki, with 3 daughters (Raley 27, Adelyn 25, and Nina 24)
- Atlas (Rhodesian Ridgeback)



Agenda

1

The Evidence Gap

Why the device approval bar isn't the same as drug approval — and what that means at the bedside

2

The Reimbursement Maze

How novel procedures get stuck — and why reimbursement inadequacy and skills gaps feed each other

3

Adoption & Diffusion

Why pharma reaches peak penetration faster — and what endoscopy can borrow

4

The Path Forward

Digital endoscopy, real-world evidence, and where clinicians hold the leverage

Pharma and MedTech both aim to put better tools in clinicians' hands.

Yet they operate with fundamentally different systems for evidence, access, and adoption.

That gap has real consequences and in endoscopic oncology.

Where the choice is between organ-sparing resection and surgery, it is a cancer care access gap, not just a systems inefficiency.

~\$360B

global medtech market, 2024

15 yrs

pharma's lead in post-market surveillance

<5%

of eligible U.S. cases reach ESD vs. 80%+ in Japan

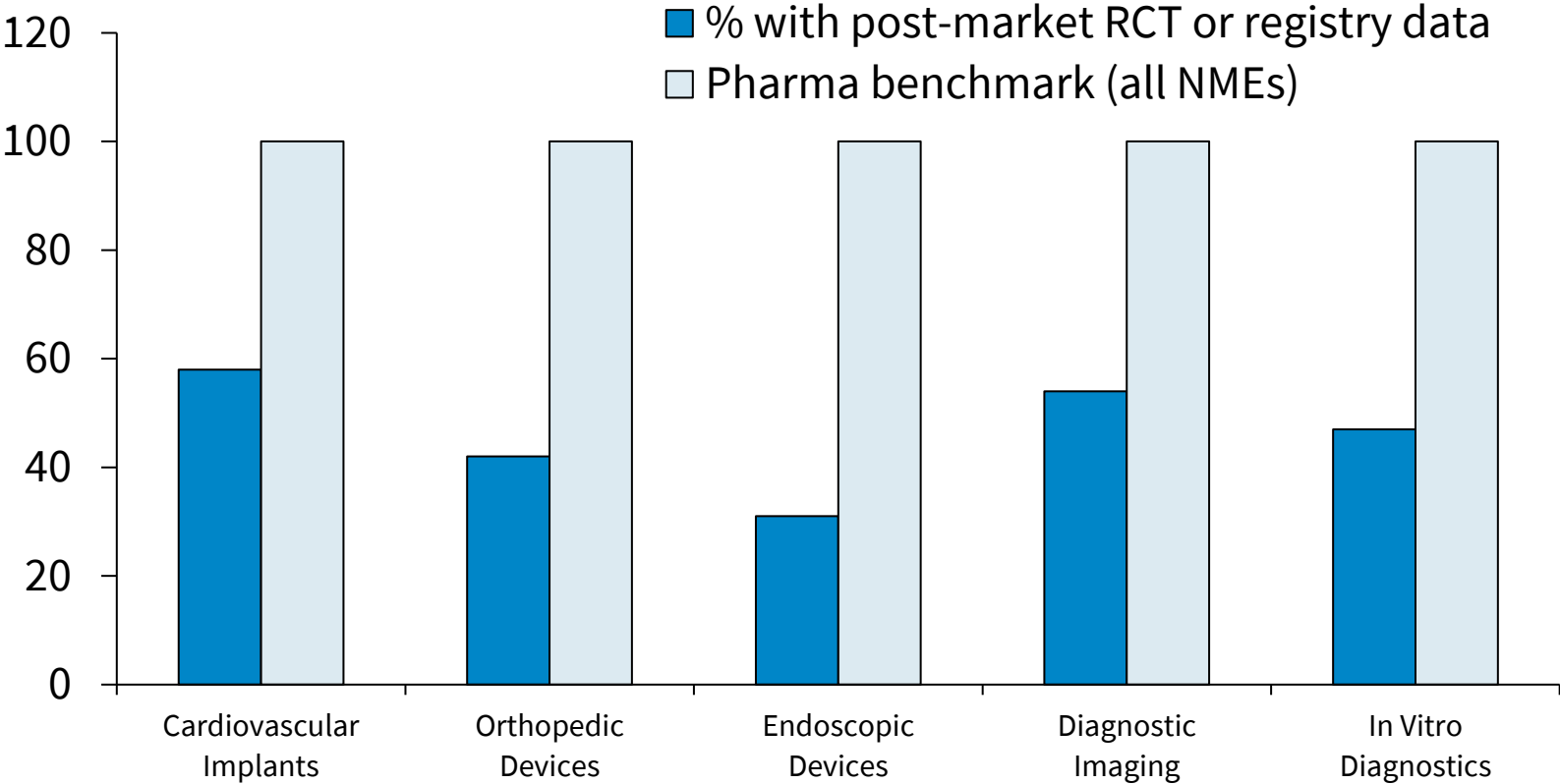
01 | The Evidence Gap

The approval bar for devices is not the same as for drugs

Evidence package at launch is fundamentally different for pharma vs. Medtech

Pharma Pathway	VS	MedTech 510(k) Pathway
✓ Phase I → II → III RCTs required		△ Substantial equivalence to a predicate
✓ Clinical endpoints (survival, remission, QoL)		△ No clinical trial required in most cases
✓ Head-to-head vs. standard of care		△ Biocompatibility & bench testing typical
✓ Post-market pharmacovigilance (REMS)		△ Post-market reporting voluntary for many
✓ Health economics pre-submission norm		△ HEOR often built after — not before — launch
✓ FDA review: 10+ months standard		△ FDA clearance in weeks (vs. months)
Takeaway: When a new endoscopic device arrives in your center, the evidence base that got it there may be far thinner than you might suspect.		

Endoscopic Devices Have the Weakest Post-Market Evidence of Any Device Category



NOTE: NME is New Molecular Entities

Source: Zuckerman et al. JAMA Internal Medicine 2014; FDA device database; Deloitte analysis — figures illustrative of published ranges

~85%

of devices cleared via 510(k)
without RCT data

31%

of endoscopic device categories
have any post-market registry

2x

faster evidence generation in
pharma vs. device sector

02 | The Reimbursement Maze

Cleared by FDA. Economically viable? Not always.

Pharma Builds the Payer Case Before Launch. MedTech Builds It After...If at All

Pharma: Drug Approval → Coverage

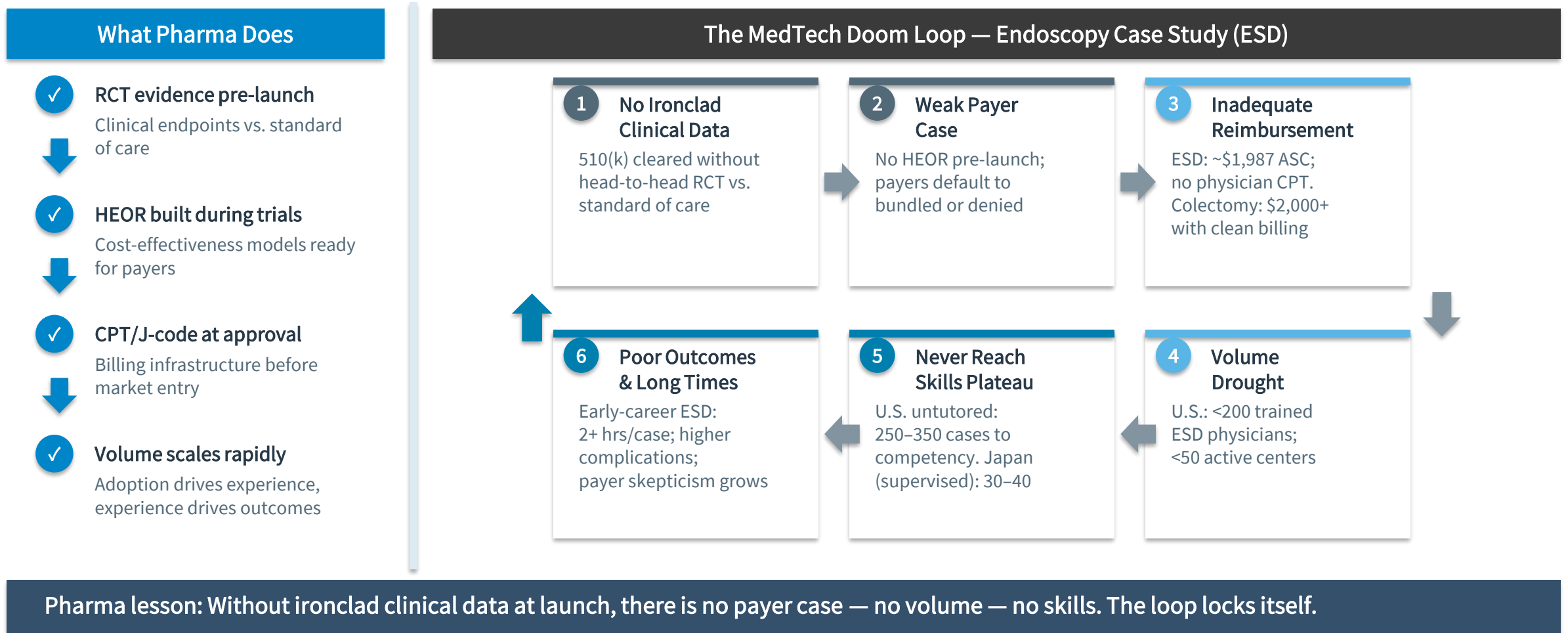
- 1 FDA Approval**
NDA/BLA with Phase III data
- 2 J-code Issued**
NDC enables immediate billing
- 3 Formulary**
Payer P&T reviews (3–6 mo)
- 4 Peak Penetration**
~5 years post-approval

MedTech: Device Clearance → Coverage

- 1 FDA 510(k) Clearance**
Substantial equivalence, no RCT
- 2 No immediate CPT code**
Procedure may be bundled or denied
- 3 Coverage w/ Evidence Dev.**
CED pathway — years of data collection
- 4 CPT / APC Assignment**
CMS recognizes standalone reimbursement

Takeaway: Pharma builds the payer case before launch. Most medtech companies build the clinical story first — and pay for it later.

The MedTech Doom Loop: How Weak Evidence at Launch Locks In Almost Every Downstream Problem



The RVU Structure Doesn't Properly Reward Complexity and APAC's Salaried Model Explains the Gap

U.S. Physician Economics: The 2-Hour ESD Problem

Procedure	Time	Physician Payment	wRVUs	RVUs/hr
Diagnostic colonoscopy	30 min	\$165	3.18	~6.4
Colonoscopy + polypectomy	35 min	\$200	4.46	~7.6
4× colonoscopies (2 hrs)	2 hrs	\$660–800	~14–18	~7–9
ESD — hospital outpatient	2 hrs	\$1,987*	unlisted	variable
Right colectomy (surgery)	2–3 hrs	\$2,000+	20–23	~7–10

* Hospital APC only (C9779, 2021). No physician CPT — unlisted codes; 8.3% denial rate.

An endoscopist choosing between a 2-hr ESD and 4 colonoscopies faces a rational economic choice. The RVU math says: do the colonoscopies. The payer system has encoded that preference into clinical practice.

Asia-Pacific: Why Time Isn't the Enemy

Salaried Hospital Model
Japan & Korea endoscopists earn fixed salaries — ¥16–21M/yr Japan; ₩80–120M/yr Korea. No personal financial penalty for spending 2 hours on a complex resection.

Volume Enables Competency
Japan: 13,000 gastric + 8,000 colorectal ESDs annually. Korean trainees observe 30–40 cases before touching a scope. Result: competency in 30–40 supervised cases vs. 250–350 untutored in the U.S.

Evidence Drives Reimbursement
Asian payers reimburse ESD because decades of registry data prove superior en-bloc resection, lower recurrence, and lower total cost vs. surgery. The clinical data came first. Pharma's playbook.

Skills Plateau = Faster + Safer
Expert Japanese endoscopists: >9 cm²/hr dissection, <3% complications, <60 min procedure time. This data exists because volume was never constrained by RVU economics.

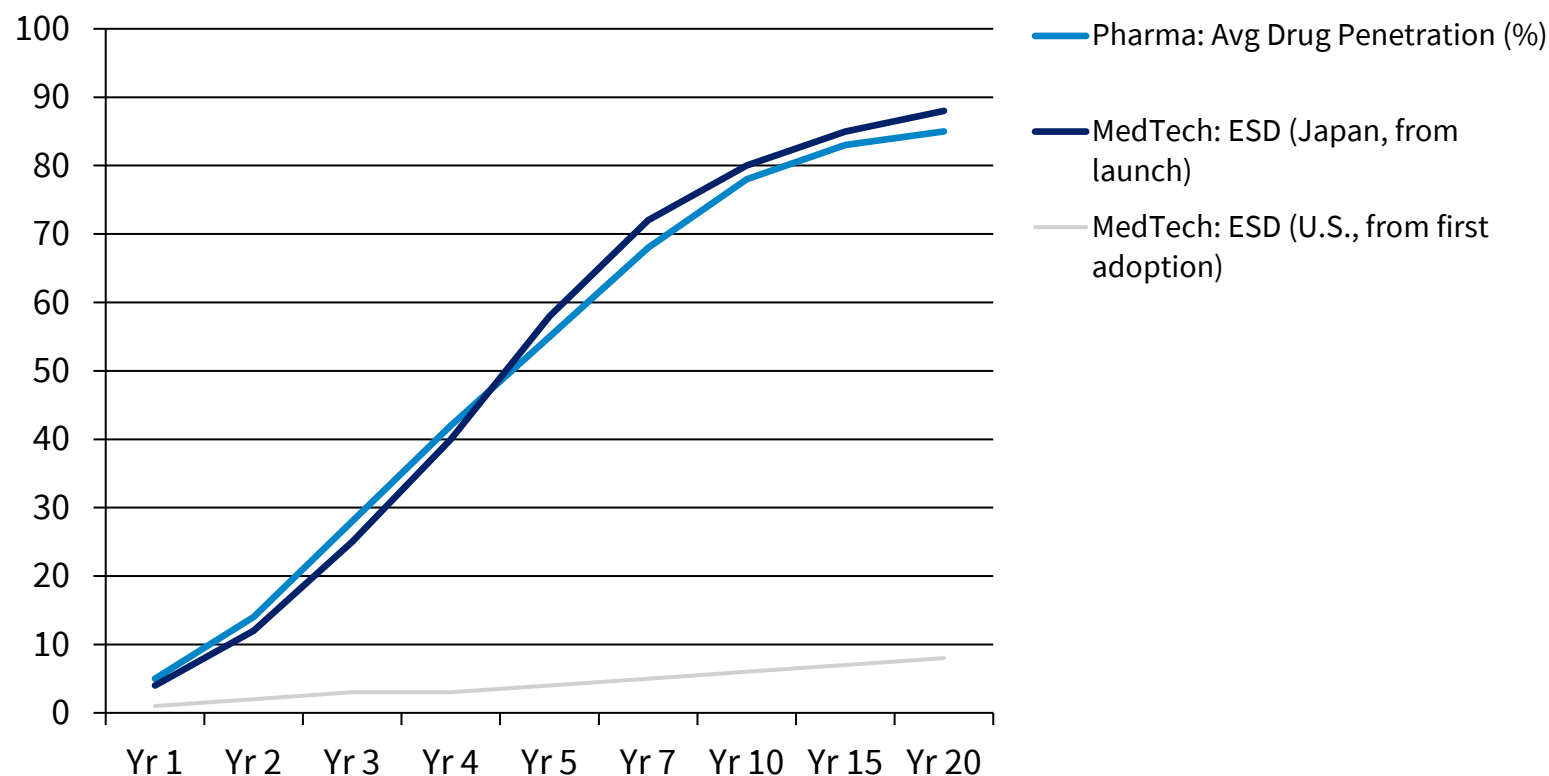
What MedTech can learn from pharma: invest in the clinical evidence that justifies the reimbursement that sustains the volume that builds the skills.

Source: CMS MPFS 2026; FastRVU GI benchmarks 2026; Khalaf et al. CGH 2024; Korea ESD PMC 2020; Japan JGES/JED; Deloitte analysis

03 | Adoption & Diffusion

Why pharma reaches patients faster — and what endoscopy can borrow

Same Procedure, Same Evidence. Japan at 85% Penetration. U.S. Still in Single Digits.



Champion Dependence

U.S. adoption requires expert endoscopists willing to train others — highly variable by geography

Training Infrastructure

No equivalent to pharma's field medical education network; proctoring programs underfunded

Reimbursement Barrier

Without clear APC/CPT value, hospitals decline to invest in training or equipment

Takeaway: Pharma systematized adoption through structured education, KOL networks, and field support. Endoscopy still relies on individual champions.

Pharma Has Four Adoption Capabilities and Endoscopy Is Behind on All of Them

1

Medical Education Infrastructure

PHARMA:

Structured MSL networks, CME sponsorship, peer-to-peer programs at scale

ENDOSCOPY:

Proctoring and simulation labs expanding — but coverage remains academic-center focused

Emerging

2

KOL & Opinion Leader Strategy

PHARMA:

KOL mapping, advisory boards, speaker bureaus integrated into launch

ENDOSCOPY:

Conference-driven; relies on early adopters; community reach limited

Early

3

Real-World Outcomes Tracking

PHARMA:

Post-market registries, claims data, EMR linkage standard

ENDOSCOPY:

GIQuIC, GQUIC building — data capture improving but not yet systematic

Building

4

Payer Engagement Pre-Launch

PHARMA:

Payer advisory boards, formulary strategies before NDA submission

ENDOSCOPY:

Reimbursement strategy typically reactive; coding delayed

Lagging

04 | The Path Forward

Digital endoscopy is closing the gap — and clinicians hold the leverage

100 Million Colonoscopies Already Happen and Digital Endoscopy Is How That Volume Becomes Evidence

~100M

colonoscopies/year in the U.S.
— natural cohort for RWE

+14%

ADR improvement with CAdE
AI-assisted detection

\$2.4B

projected AI endoscopy market
by 2028

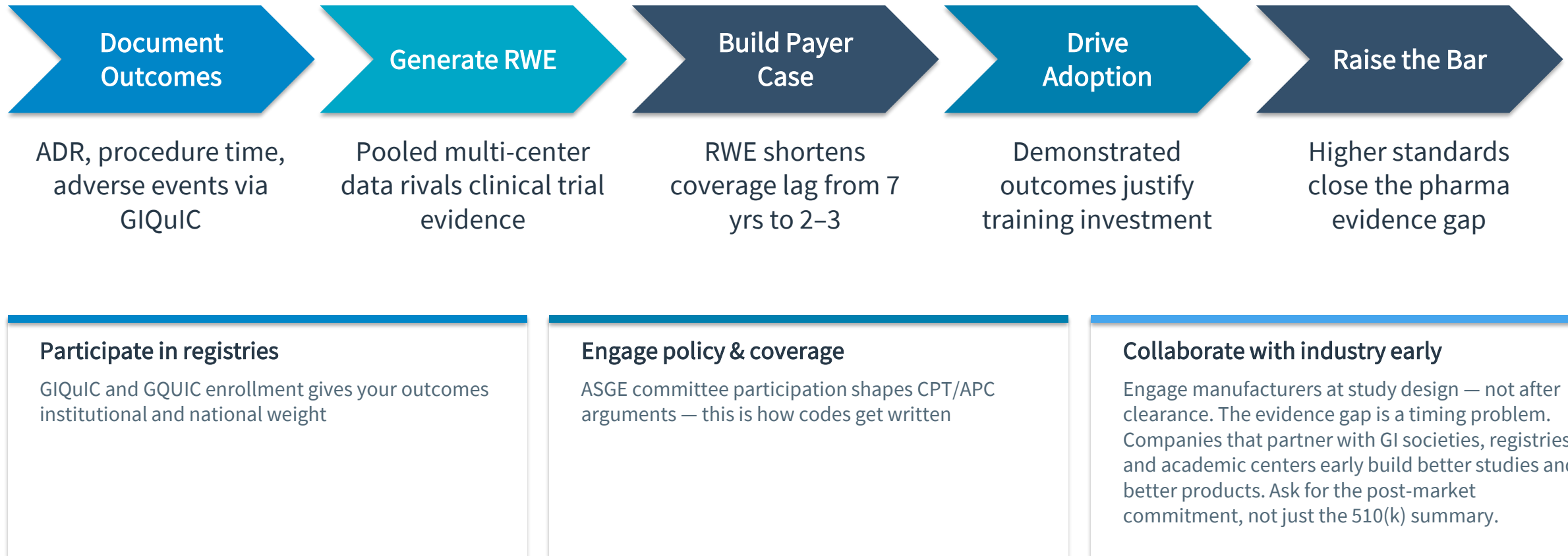
3–5x

faster real-world dataset
generation vs. traditional
registry

What Digital Endoscopy Enables

- 1 Procedure-level structured data at scale**
Every CAdE-assisted scope becomes a data point — finally rivaling pharma trial cohort sizes
- 2 Prospective outcome capture**
AI platforms embed quality metrics into workflow — not retrospective chart review
- 3 Comparative effectiveness at low cost**
Real-world head-to-head comparisons across techniques, settings, and patient populations
- 4 Faster payer case-building**
Outcome data from routine practice can support coverage negotiations within 2–3 years

The Doom Loop Runs in Reverse When Clinicians Generate the Evidence Payers Need



Source: ASGE GIQuIC; Deloitte Health strategy analysis; conference director vision: "clinicians, researchers, innovators, and industry need more opportunities to work through these questions together"

What Closing the Gap Requires: Four Things to Take From This Room

1

The evidence bar is not equal

Most endoscopic devices cleared via 510(k) have no head-to-head trial data. Scrutinize the evidence behind new tools. And recognize where pharma's RCT model doesn't fully translate — device innovation sometimes needs its own evidence path, built with the same rigor.

2

Reimbursement is a clinical strategy issue

Coverage gaps determine which patients get access. The doom loop starts with weak evidence and ends with poor outcomes. Understanding the payer pathway lets you break it.

3

The skills gap is structural — not individual

250 cases to competency without mentorship vs. 30 with it. The difference is not physician talent — it's volume infrastructure. That infrastructure is built through registries and payment reform.

4

Your data is the lever

At ~100M colonoscopies per year, GI generates enough real-world volume to rival clinical trials. Registry participation is the highest-leverage action here. The question is not whether medtech should become pharma — it is what pharma learned that we still need to build, and what we must build differently for endoscopic oncology.

Pharma spent 30 years building this.
Evidence. Access. Adoption.

The question is not whether to become
pharma.
It is what to borrow, what to build, and
what to do differently.

Thank you!



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