Promoting Biotech Innovation:

Designing Dialysis Access Trials for Payor Coverage

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FDA APPROVAL ≠ CMS COVERAGE!

- For device approval or clearance, FDA wants to see:

  "A reasonable assurance of safety & effectiveness"

- For coverage, CMS wants to know if the product is:

  "Reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"

FDA approves or clears devices. Payors drive adoption!

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A COSTLY STRATEGIC MISTAKE

Pivotal Study→ FDA → More Data → Coverage

- Time delay (12–36 months)
- Added data generation
- Increased capital burn

The most expensive trial may be the one you have to run twice!

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WHAT PAYORS NEED

Clinical Benefit:

- Does this device reduce the annual reintervention rate?
- Might it speed time to a functional access?
- Can it reduce the catheter exposure time and infection rates
- Is there late durability beyond the 6-month endpoint?

Economic Value

- Total cost of care & procedural time
- Site of service profit margin

Reimbursement follows proof of both clinical benefit & economic value

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THE SHIFT

The pivotal investigation can't just be a regulatory exercise anymore. It must also be a key part of reimbursement strategy!

That doesn't mean studies need to be larger or more complex, but it does mean being intentional about:

- Longer term follow-up when it matters
- Prospectively defining economic and utilization endpoints
- Capturing reinterventions and downstream costs
- Engaging payors early!

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CONCLUSION

- Innovation doesn't fail at FDA, but from faulty device adoption strategy
- If your pivotal study doesn't answer the payor's question, then you have arrested product development, and the market will wait!
- FDA approval gets you through the front door, obtaining coverage will determine if anybody walks through it!

Where Echelon sees the biggest gains is when regulatory and reimbursement strategies are designed together, not sequenced

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If you have any future questions, don't hesitate to reach out!

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