The Real Issue:
A Dysfunctional Research Ecosystem

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Why Discuss the Research Ecosystem?

- Our willingness to both understand and work to change the research ecosystem is what differentiates OM from other advocacy groups

- We have talked about many of these inefficiencies before; however, we all need to agree that we support for OM's Open Science Principles

- The "inefficient" can be made efficient if we can demonstrate that stressing the following principles can yield advancements that can quickly benefit the patient:
  - ✓ Unrelenting patient focus
  - ✓ Focus on data sharing and data quality
  - ✓ Emphasis on big science de-risked by requiring deliverables for continued funding
  - ✓ Deemphasize the primacy of peer reviewed journal articles while making successful coordination with the FDA the primary measure of professional accomplishment
  - ✓ Emphasize team science and multi-institutional collaboration

- And finally, we must understand that the approval of better diagnostics, treatments and cures does not solve the problem – acceptance by medical professionals can take over a decade(s) unless new strategies for dissemination are found.

The Rational Clinical Research Ecosystem

The Way Most People/Donors Believe It Works

Bench/Basic Science	"Translational Science"	"Bedside"
Starts With A Hypothesis	Research Findings to Patient Benefits	Better Diagnostics, Treatments & Cures

Hypothesis: New applications of MRI can diagnose "mild" and "moderate" TBI (non CT positive) and identify those who will suffer long lasting symptoms

- Patient/Translation focused
- Collaboration required
- Research fully funded to prove or disprove hypothesis
  - ✓ Required "N" (large enough)
  - ✓ Data curation
  - ✓ Data Storage
  - ✓ Data analysis
  - ✓ All agreed requirements
- CDISC common data standards used
- Data shared
- Deliverables identified and monitored
- IP respected but not a barrier to translation
- All results reported and tracked

- Patient/Bedside focused
- Large enough numbers ("N") achieved
- Engagement with the FDA encouraged and rewarded
- Clinical trials de-risked
- Better diagnostics, treatments and cures are the priority
- Peer reviewed journal articles not the measure of success
- Additional funds provided for meeting deliverables
- Team science rewarded
- IP shared
- All results reported and tracked

- Patient focused
- FDA approval of better diagnostic, drug, device, treatment
- CPT code issued for insurance reimbursement
- Immediate dissemination of findings so all patients are aware and benefit
- Researchers rewarded for helping patients
- Team science rewarded
- All data shared
- All results reported and tracked

Today's Clinical Research Ecosystem

A Model Of Inefficiency

Bench/Basic Science	"Translational Science"	"Bedside"
Starts With A Hypothesis	Research Findings to Patient Benefits	Better Diagnostics, Treatments & Cures

17 years to adoption

Hypothesis: New applications of MRI can diagnose "mild" and "moderate" TBI (non CT positive) and identify those who will suffer long lasting symptoms

- Researcher/Patient focused
- Policies discourage collaboration
- Research partially funded to prove or disprove hypothesis
  - ✓ Small "N" the norm (large enough)
  - ✓ Data curation not funded
  - ✓ Data Storage not funded
  - ✓ Data analysis not fully funded
  - ✓ Other requirements not funded
- CDISC common data standards not funded or required
- Data sharing discouraged
- Deliverables not identified or required
- IP is a barrier to translation
- Only positive results reported and tracked

- Researcher/Patient focused
- Large enough numbers ("N") not achieved without another grant
- Engagement with the FDA discouraged and not rewarded
- Clinical trials too risky
- Better diagnostics, treatments and cures are not the priority
- Peer reviewed journal articles are the measure of success
- Additional funds provided based on the number of peer reviewed journal articles
- Team science discouraged
- IP is a barrier to "bedside"
- Only positive results reported and tracked

- Profit/Patient focused
- FDA approval of better diagnostic, drug, device, treatment difficult because data standards not enforced
- CPT code for insurance reimbursement uncertain because FDA approval deferred or denied
- It takes 17 years for the dissemination
- of findings so all patients are aware and benefit
- Researchers are rewarded for the publication of journal articles
- Team science discouraged
- Data is not shared
- Only positive results reported and tracked