

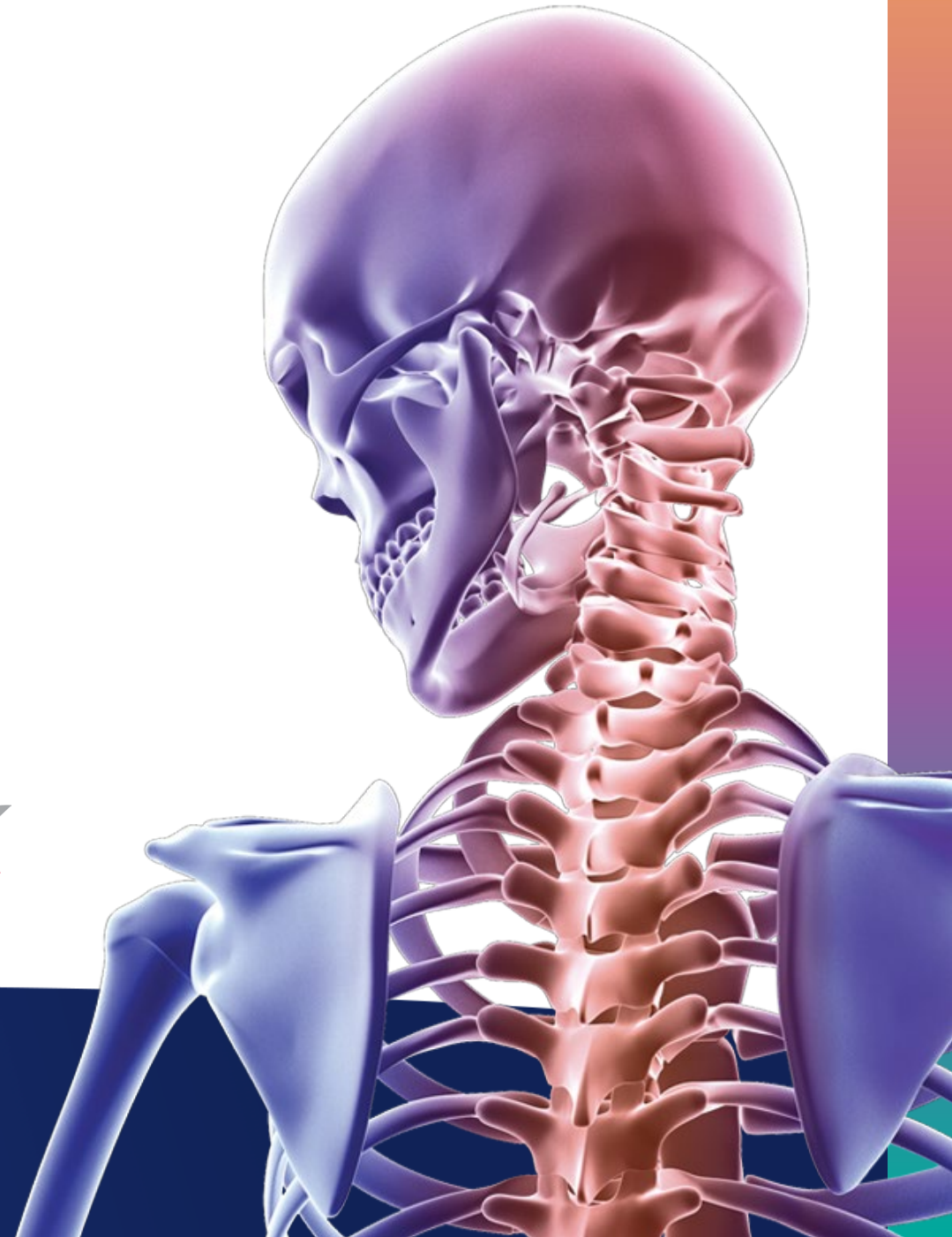
Speeding Innovation Through Streamlined Regulatory Tools

Brianna Prindle, restor3d

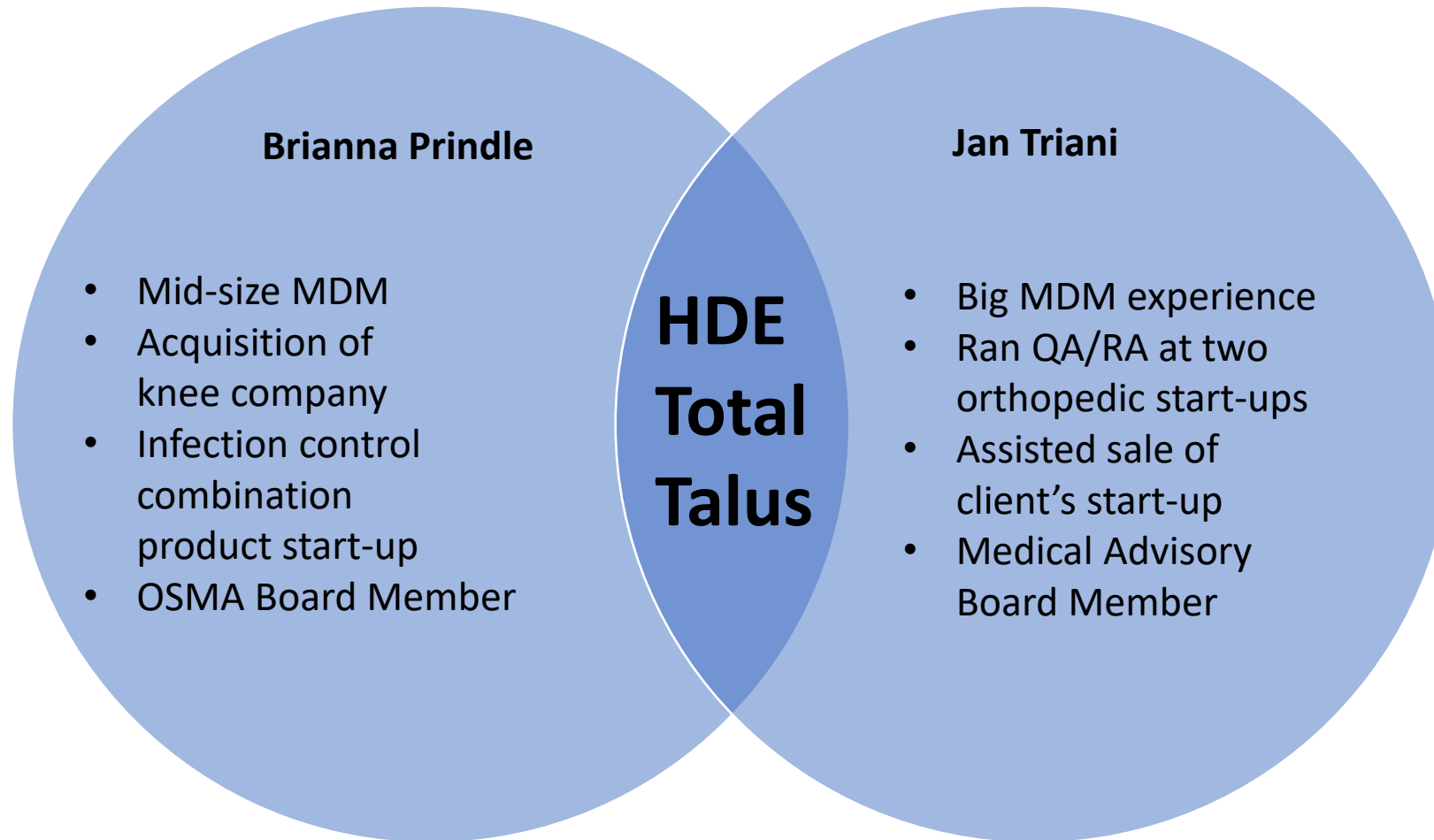
Jan Triani, Triani Consulting

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Background and experience



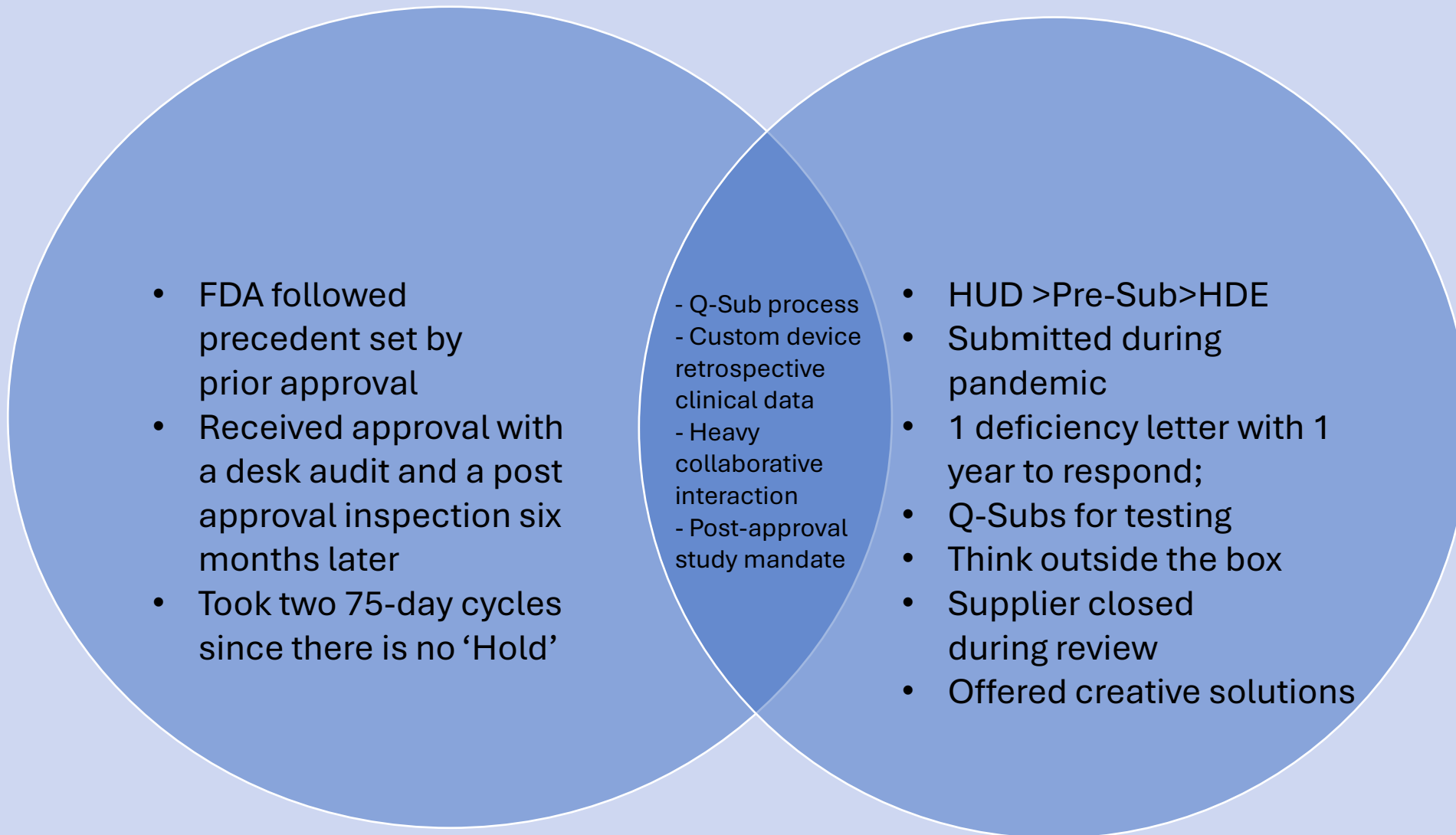
Existing Regulatory Tools for Novel Devices

- Humanitarian Device Exemption
- Pre-submissions
- Breakthrough Device Designation and Sprint Discussion
(Previously the Expedited Access Pathway)

Humanitarian Device Exemption

- Clinical indication affects <8,000 US patients annually
- Regulatory pathway for rare disease or condition
- Proves benefit > risk
- Demonstrates safety and probable benefit, not effectiveness
- Required to submit QMS elements, supplier information and testing
- Audits of legal manufacturer part of approval process
- Post-approval study mandate is common

HDE Experience with FDA



Pre-Submissions: Things to consider

- What is the purpose?
- Do you have feasibility data?
- Test plans or rationale?
- Timing is important

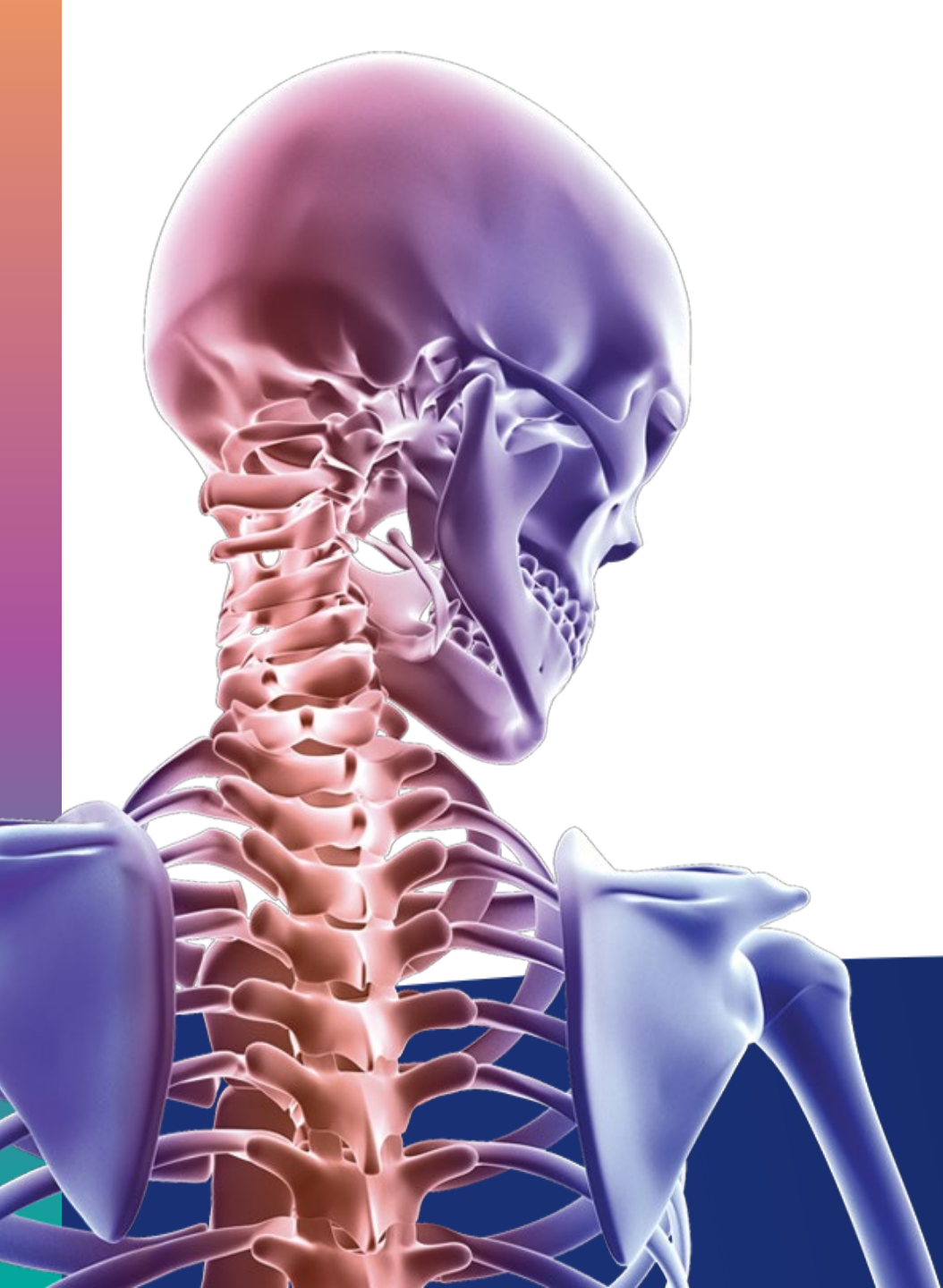
Breakthrough Device Designation and Sprint Discussions

Process

- FDA grant/deny request for BDD in 60 calendar days
- 10 to 1 conversion rate. As of Sept 2024, CDRH granted 1,029 BDDs with 124 achieving clearance or approval.¹
- Only 137 orthopedic BDDs granted and 17 approvals

Benefits

- Single-topic Q-sub on a 45-day cycle
- Priority review/management involvement
- Additional collaboration with FDA

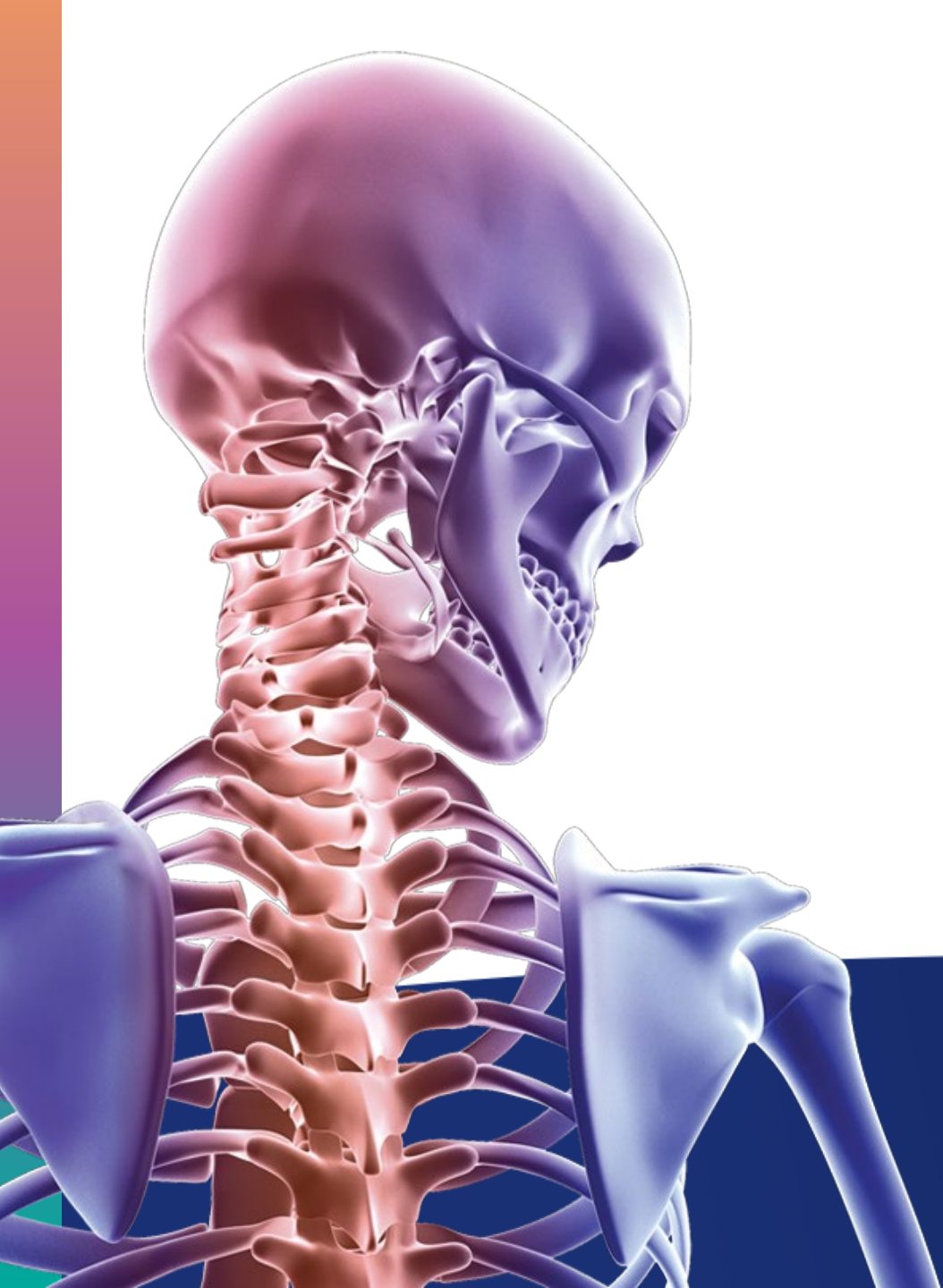


Thank You

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Thank You for Attending!

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