# Real-World Readiness Checkpoint – Fast Track

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| ABCDS Oversight Governance Principle | Potential Supportive Evidence |
| General/Summary | Recommendation and rationale to proceed with development or deployment:* Brief executive summary of conclusions regarding clinical value & safety, usability, fairness, and regulatory standing
* Overall risk/benefit assessment, including potential impact of false positives, false negatives, hallucinations, or other unexpected output
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| Clinical Value & Safety | * Description of methods, results, and conclusions on safety, efficacy, fairness, and equity (risk-benefit analysis) based on prospective data
* Brief summary of methods and results from clinical validation of the tool on a small, representative cohort of patients (e.g. chart review)
* Updated risk analysis and mitigation strategies
* Brief assessment of data flow, quality, and missingness
* Maintenance/Monitoring plan, including:
	+ Description of selected performance, fairness, equity, and impact metrics with rationale
	+ Data quality metrics
	+ Adoption measures for each use case (may be qualitative)
	+ Recommendation on monitoring frequency
	+ Criteria for sunsetting or updating the tool

For FDA-cleared algorithms:* Test environment validation results
* Calibration data and configuration information

\*based on control data  |
| Fairness & Equity |
| Usability, Reliability & Adoption |
| Regulatory Compliance | * Training plan and materials (including QA for imaging algorithms)
* Screenshots of the interface

If applicable:* Materials supporting regulatory assessment including direct input and/or collaboration with the Duke Office of Regulatory Affairs and Quality (ORAQ)and/or FDA
* Finalized commercialization plans/agreements for external use of algorithms developed at Duke

*\*\*Note that the Review Committee may require an approved IRB protocol for implementation prior to clinical use.* |
| Transparency | * Completed or updated ABCDS registration form
* Model fact sheet with instructions for access by end users
* Documentation of any changes potentially affecting the regulatory pathway, e.g. model inputs, interface, recommended threshold(s), actions/decisions the tool is intended to support, etc.
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# FTm Checkpoint Review

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| ABCDS Oversight Governance Principle | Potential Supportive Evidence |
| General/Summary | Recommendation and rationale to proceed with development or deployment:* Brief executive summary of conclusions regarding clinical value & safety, usability, fairness, and regulatory standing
* Overall risk/benefit assessment, including potential impact of false positives, false negatives, hallucinations, or other unexpected output
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| Clinical Value & Safety, | * Brief summary of methods and results from clinical validation of the tool on a small, representative cohort of patients (e.g. chart review)
* Current monitoring report highlighting main findings on prospective model performance, clinical impact, and adoption
* Updated monitoring plan (if needed)
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| Fairness & Equity |
| Usability, Reliability & Adoption |
| Regulatory Compliance |
| Transparency | * Completed or updated ABCDS registration form

If applicable:* Documentation of any changes potentially affecting the regulatory pathway, e.g. model inputs, interface, recommended threshold(s), actions/decisions the tool is intended to support, etc.
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