# 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 |
| 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. |

# 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 |
| 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) |
| 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. |