The Future Is Remote: FDA Guidance and Regulatory Strategy for RPM in Drug Research

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Regulatory Aspect of Drug Development

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Introduction

- Definition of RPM
  - Technologies that collect and transmit health data from patients outside of traditional settings.
- Why it's relevant
  - RPM tools are now influencing trial design, drug safety monitoring, and real-world evidence generation.
- Transition
  - These technologies fall under increasing FDA oversight, especially when they affect treatment decisions.

FDA’s Regulatory Scope Over RPM

- RPM devices may be considered:
  - **Medical Devices** (FDA regulates under CDRH)
  - **Clinical Decision Support (CDS)** tools (regulated under 21st Century Cures Act)
  - Part of **Drug Development Tools (DDTs)** if used in trials
- Key FDA Guidance:
  - **“Policy for Device Software Functions and Mobile Medical Applications” (2023)**
  - **“Clinical Decision Support Software” (2022 Final Guidance)**
  - **DDT Qualification Programs**

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Regulatory Pathways for RPM Involvement in Drug Development

- RPM can support drug development by:
  - Enabling **decentralized trials**
  - Monitoring **safety signals (e.g., BP, glucose, ECG)**
  - Capturing **real-world evidence (RWE)** for regulatory submissions

- Potential pathways:
  - **Pre-Submission (Q-Sub)** for investigational use
  - **SaMD (Software as a Medical Device)** if used independently of a drug
  - **Combination Product** if co-packaged with a drug

Key Risk-Based Regulatory Principles

- **Risk Classification**: Based on intended used and risk to patients
- RPM's regulatory burden increases when:
  - The software makes autonomous clinical recommendations
  - It affects enrollment, treatment, or safety decisions
- Refer to:
  - **IMDRF SaMD Framework**
  - **FDA Digital Health Guidance Suite**

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Real-World Use Case

- Use a public example (e.g., wearable RPM in COVID-19 clinical trials or monitoring QT prolongation in oncology)
- Tie in FDA's **RWE Framework (2018)** and updated **RWD/RWE guidance (2023)**
- These devices contributed data used in regulatory decision-making

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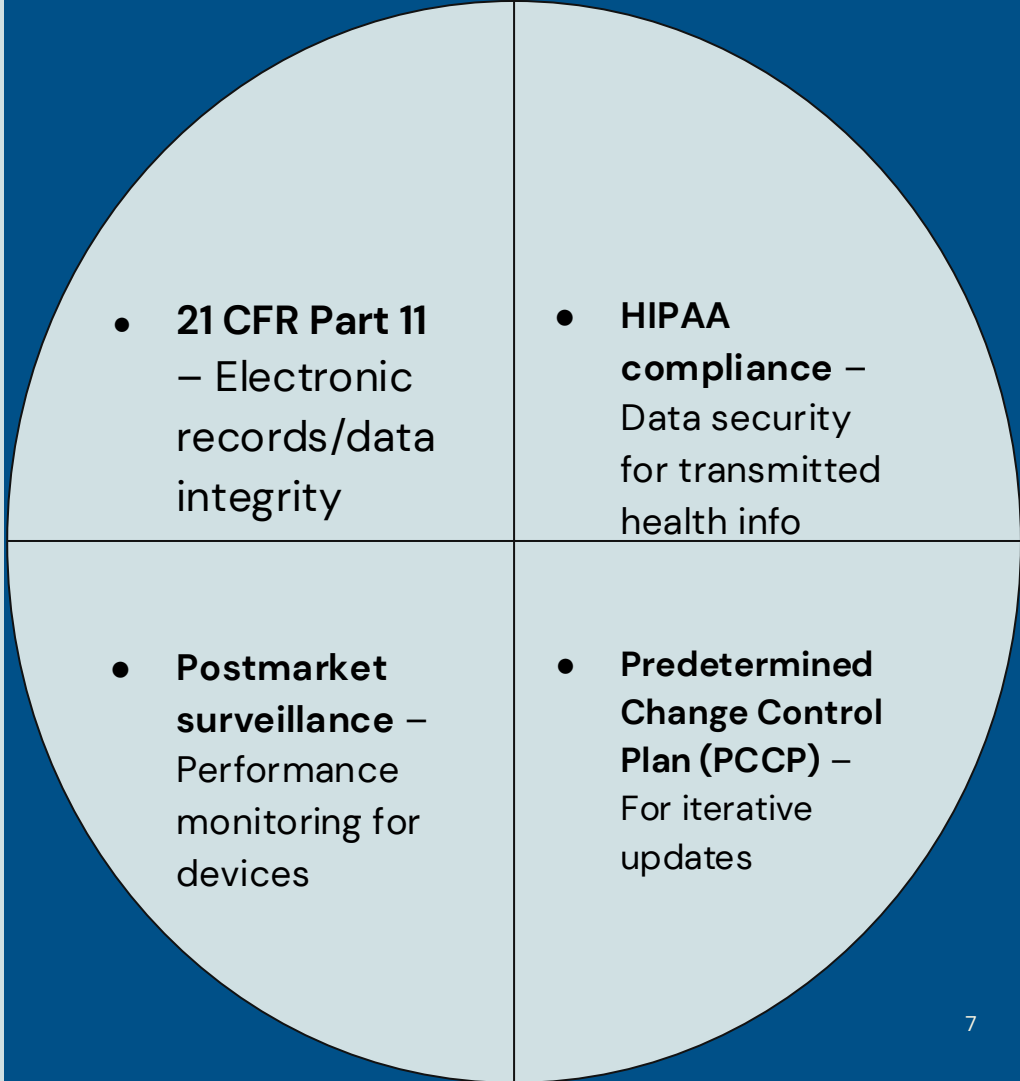
Regulatory Considerations and Safeguards

- RPM tools must meet specific key compliance requirements:



Future Directions

- FDA's **Project Polaris** – Aligning digital health oversight across centers
- RPM expected to play a larger role in:
    - Adaptive trial designs
    - Pharmacovigilance
    - Real-time intervention in high-risk drug therapies
- Investment in **interoperability (FHIR)** and FDA's focus on transparency

Conclusion

- RPM is reshaping how we gather and apply clinical data
- Regulatory clarity is key to adoption: FDA's guidance documents offer structured pathways
- These technologies promise better safety, efficiency, and equity in drug development — when appropriately validated

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References

- U.S. Food and Drug Administration. *Clinical Decision Support Software: Guidance for Industry and FDA Staff*. Final guidance. September 2022. Accessed April 10, 2025. https://www.fda.gov/media/109618/download
- U.S. Food and Drug Administration. *Policy for Device Software Functions and Mobile Medical Applications: Guidance for Industry and FDA Staff*. Final guidance. September 2023. Accessed April 10, 2025. https://www.fda.gov/media/80958/download
- U.S. Food and Drug Administration. *Real-World Evidence Program: Framework for FDA's Use of Real-World Evidence to Support Regulatory Decision-Making*. December 2018. Updated February 2023. Accessed April 10, 2025. https://www.fda.gov/media/120060/download
- U.S. Food and Drug Administration. *Drug Development Tool (DDT) Qualification Programs*. Updated March 2024. Accessed April 10, 2025. https://www.fda.gov/drugs/development-approval-process-drugs/drug-development-tool-qualification-programs
- U.S. Food and Drug Administration. *Software as a Medical Device (SaMD)*. Accessed April 12, 2025. https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd

References

- U.S. Department of Health and Human Services. *Summary of the HIPAA Privacy Rule*. Updated March 2022. Accessed April 10, 2025. https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html
- U.S. Food and Drug Administration. *21 CFR Part 11 - Electronic Records; Electronic Signatures*. Revised April 2024. Accessed April 10, 2025. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11