

MRD as a Primary Endpoint for Accelerated Approval in Multiple Myeloma



A new regulatory milestone

The FDA published draft guidance on using minimal residual disease (MRD), also known as measurable residual disease, as primary endpoint to support the potential accelerated approval of novel treatments for multiple myeloma (MM).

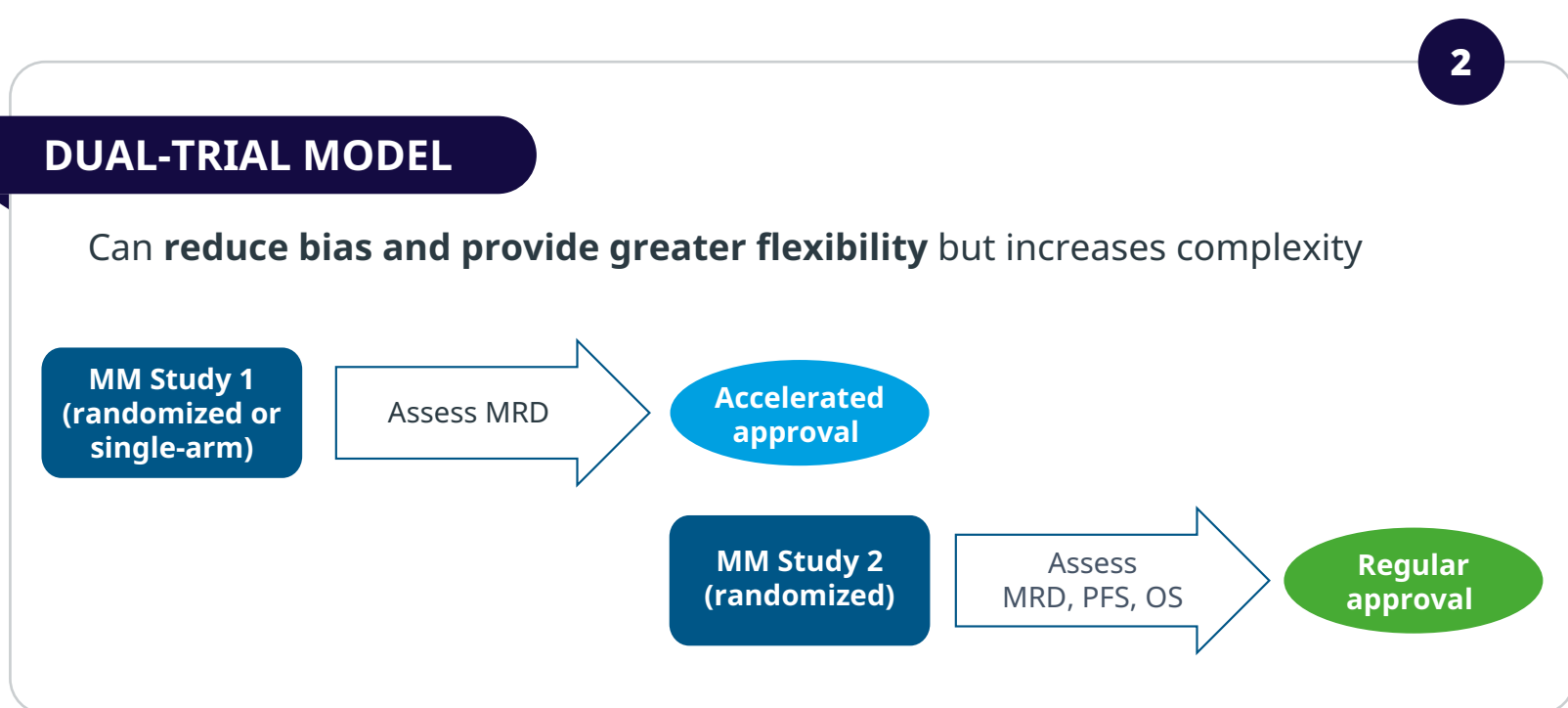
Why this matters

- Increasing survival and stronger response rates make differentiation harder
- MRD enables earlier differentiation and can support faster development timelines

What the draft guidance enables

- MRD negativity in complete response may serve as a reasonably likely surrogate for progression-free survival for accelerated approval, provided evidentiary and assay validation standards are met

Trial design options in accelerated approval pathway



PFS: Progression-Free Survival
OS: Overall Survival

MRD execution



MRD timing, threshold, and population must be prespecified



Statistical analysis plans must clearly define endpoints and analysis approach



Assay processes must be controlled across the full workflow

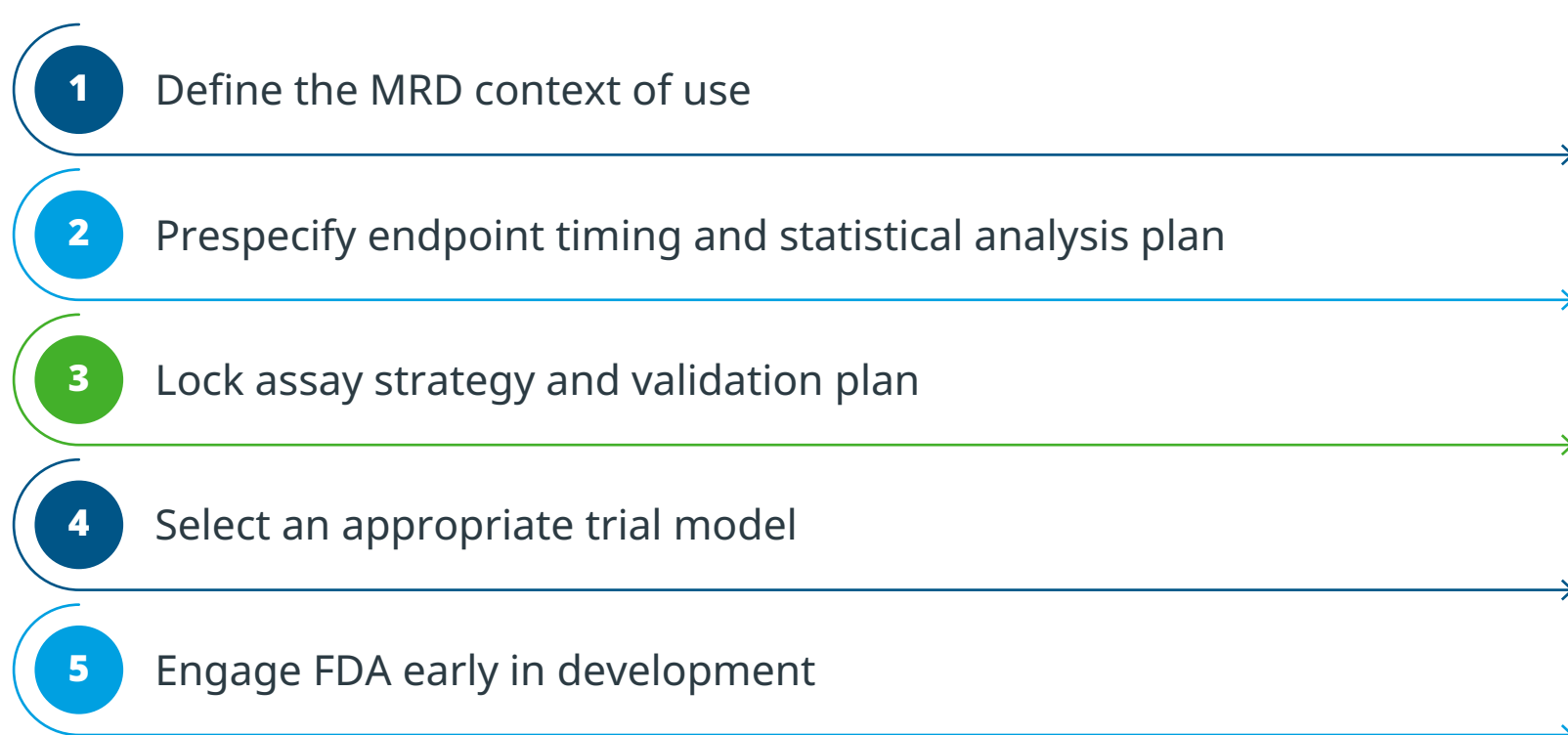
Assay expectations

- Validation should demonstrate **accuracy, precision, detection limits, stability, and specificity**
- A **single validated technology** such as next-generation flow (NGF) or next-generation sequencing (NGS) should be used

Accelerated approval expectations

- Confirmatory trials** are expected early, often before or at approval
- Operational readiness and study feasibility** are assessed by regulators
- On-going progress reporting** is required post-approval

MRD endpoint readiness in 5 steps



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