

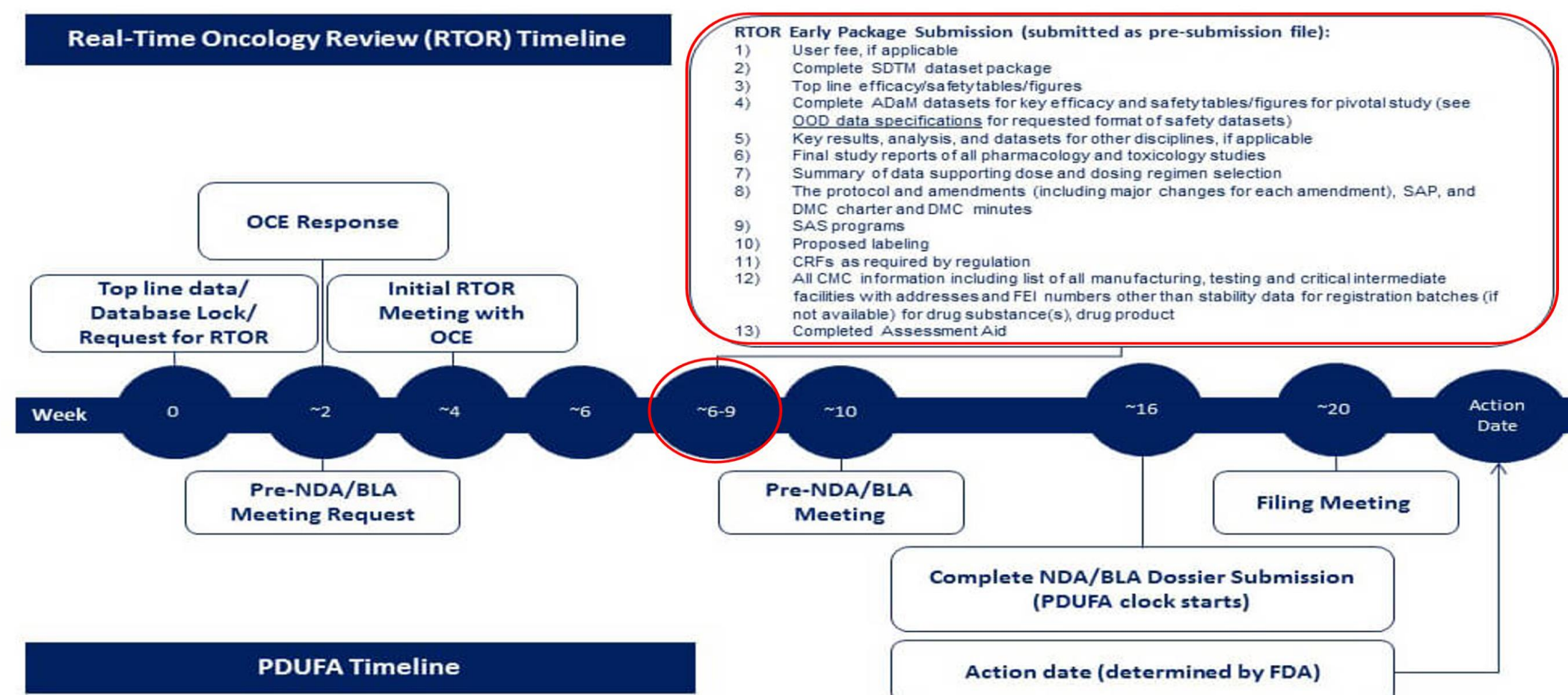
Process Optimization for Submissions Participating in the FDA's Real Time Oncology Review Pilot Program

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Abstract

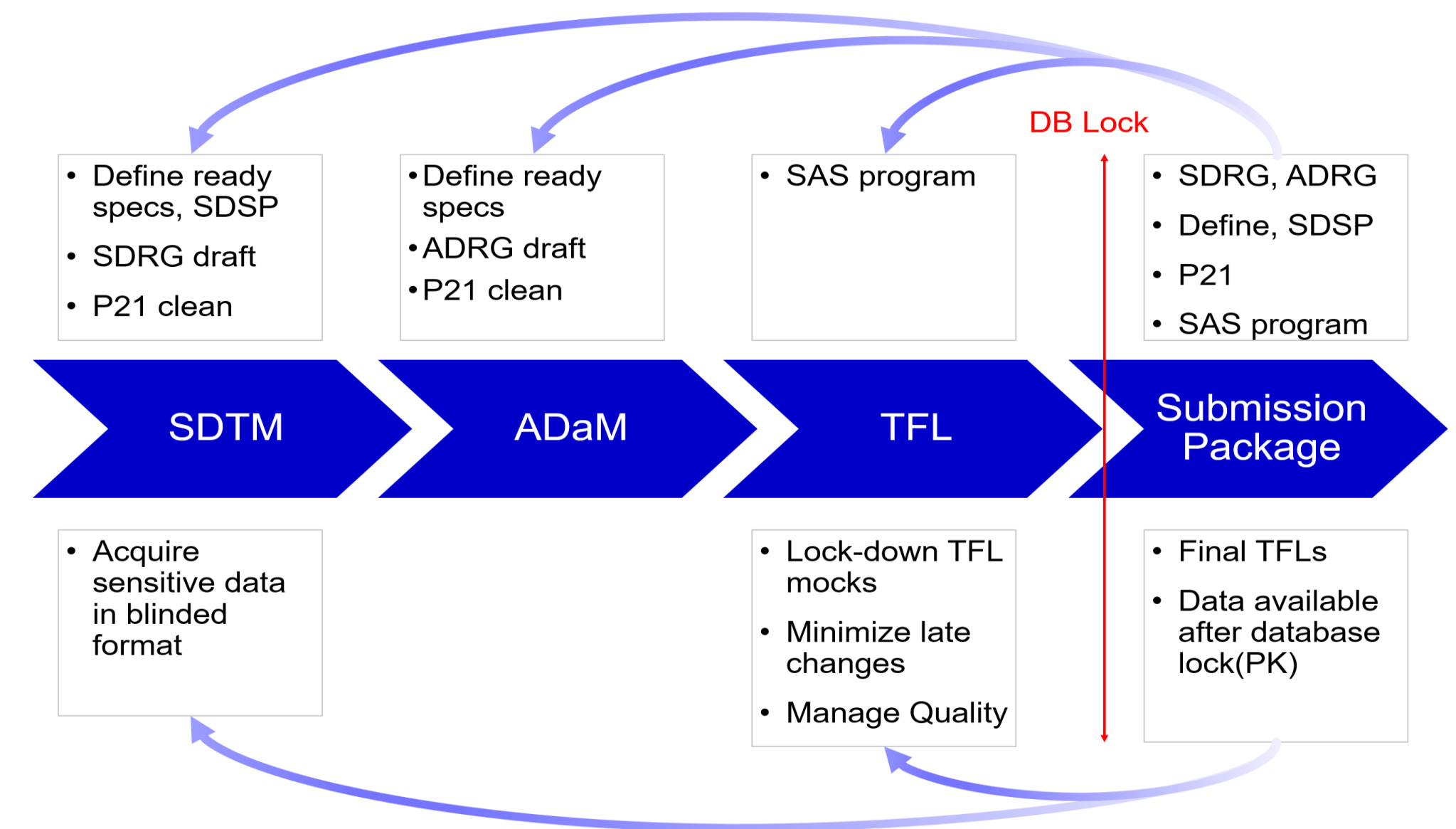
Pfizer has successfully completed several submissions participating FDA Real Time Oncology Review (RTOR) pilot program. To meet RTOR timelines, we have optimized operation process to plan and prepare submission package in advance in order to reduce cycle time. Study Data standardization Plan (SDSP) is created and communicated with FDA in type B/C meeting to clarify final data format. Pinnacle 21 (P21) report is run on regular basis from study start up to proactively address data issues in time and prepare final P21 report with minimum turnaround time. Before final database lock, technical documents in submission package such as Review Guide and Define.xml are completed to maximum, only need minor update once final data is available; PK and biomarker data in blinded format is made available for programming related outputs and completing technical documents. All CSR tables and datasets are submitted together to FDA for RTOR review.

FDA Proposal for Marketing Application Timeframe of Real-Time Oncology Review (RTOR)



* The diagram reflects a general timeline suggestion. Companies should discuss with FDA their submission proposal.

Process Optimization for RTOR Submissions



Goal: Reduce Cycle Time After Database Lock

- Specify RTOR deliverables and plan early
- Prepare submission package components before database lock
- Avoid late changes to programming deliverables
- Avoid re-work due to quality deficiency