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# Generic Drug Assessment Communication Mechanisms & Strategies to Facilitate Timely Approval



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# Our initial response is positive ...



Timely status updates about complex issues



Summary updates from all disciplines



Improved ability for timely launches



Efficient post CRL Scientific meetings

**...transparency pilot to become the way of working and requires systemic approach**

# Our Ask – Real Time Communications



Timely issuance of more IRs/DRLs & minimizing goal date extensions



Early identification & communication of complex issues and avoiding late CRLs



Flexible communication mechanism to discuss complex issues



Continued support from RPM and smooth handover for any changes



# Seeding for the Future



Create an Electronic Dashboard for Submission Tracking System-Industry Access



Status Update Review by Discipline including DMF deficiency status



Significant Dates (e.g review milestones, expected decision dates, GDUFA dates.....)



Facility Status

## Key Focus Areas

Create a user-friendly, secure, online database/portal/platform that provides real-time updates on the status of ANDA reviews

Q & A



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