

Real Time Oncology Review Pilot Program: A Novartis & Roche Perspective

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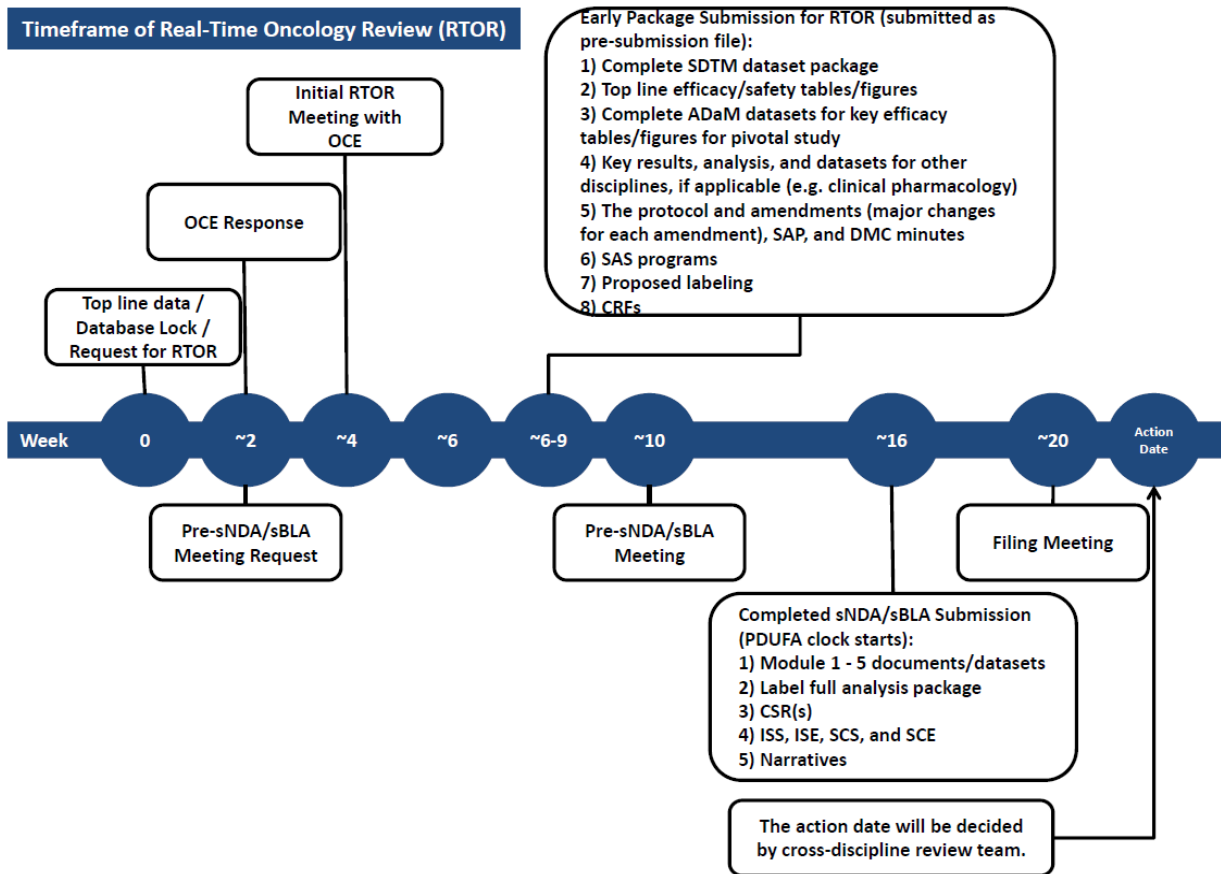
Agenda

- What is RTOR?
- Kisqali Experience
- CLL14 Experience
- Challenges & Opportunities
- Recommendations

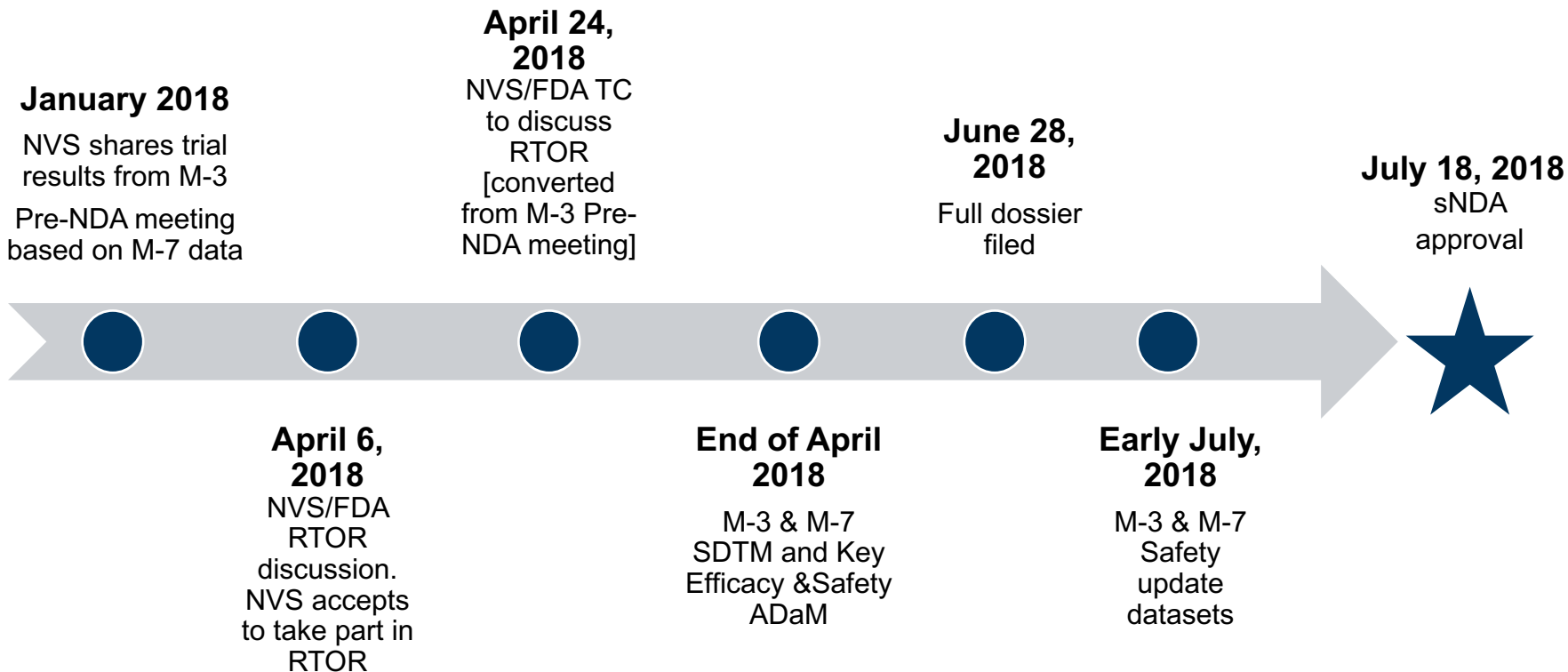
What is RTOR?

- Real-Time Oncology Review pilot program launched by FDA
- Provides early engagement between FDA and applicant by submitting key efficacy/safety outputs/data prior to full application submission
- Eligibility criteria e.g. drugs likely to demonstrate substantial improvements over available therapy; straight forward study designs; endpoints that can be easily interpreted etc.

RTOR Pilot Timeframe

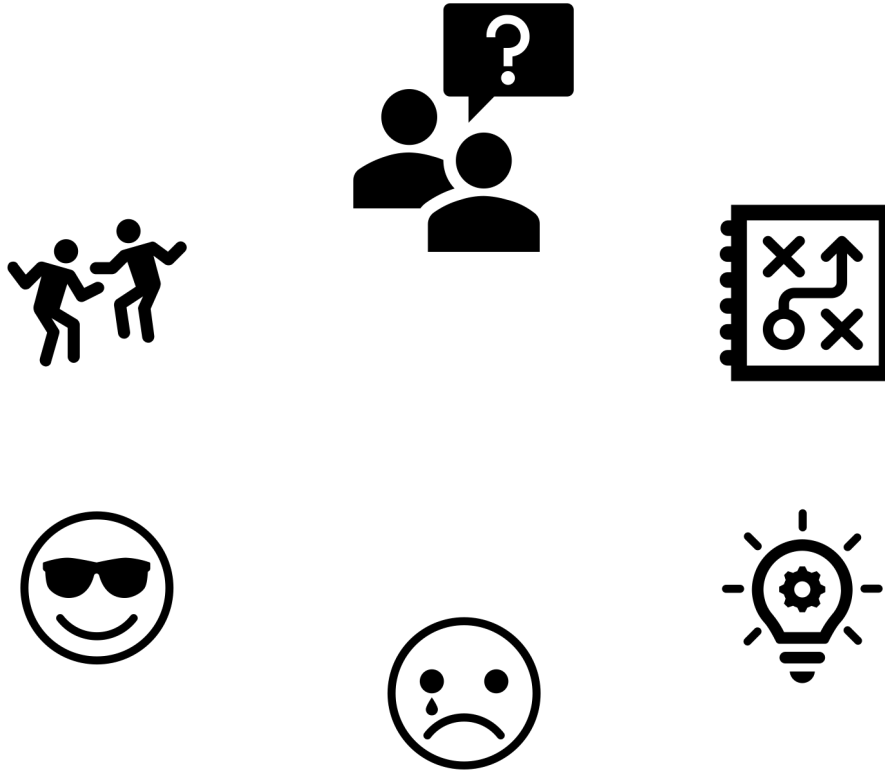


Kisqali Key Timelines



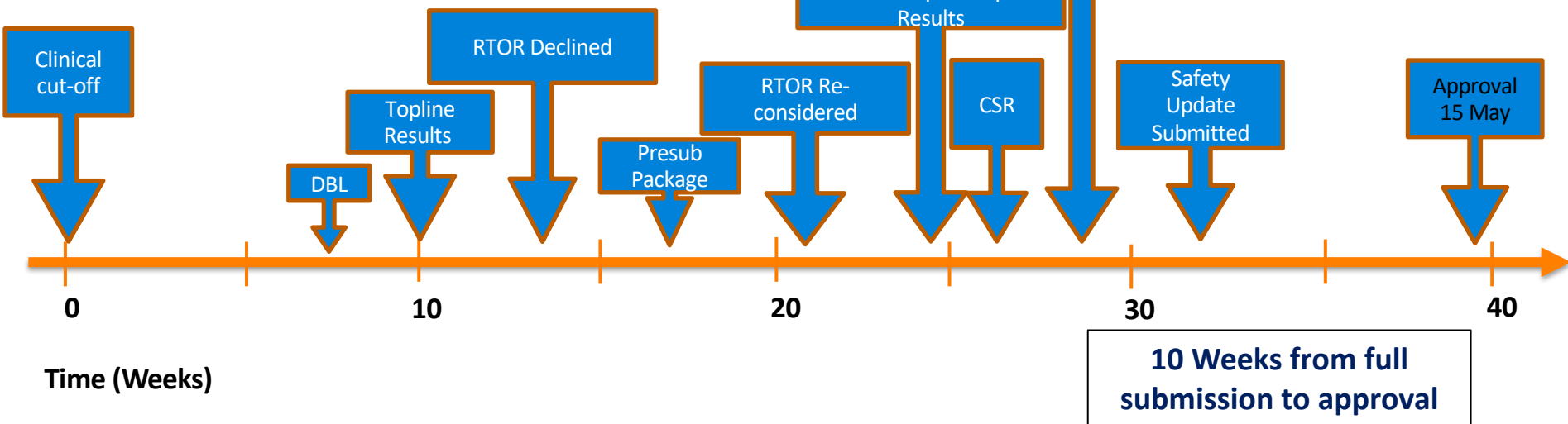
Venclexta RTOR Considerations

Roche



Venclexxa Filing Key Milestones (weeks)

Milestone	Date
Clinical Cutoff	17 Aug 2018
Topline Results	26 Oct 2018
RTOR declined	09 Nov 2018
Presubmission Package	14 DEC 2018
RTOR reconsidered	11 Jan 2019
Early Package Submission	06 Feb 2019
CSR Submission	12 Feb 2019
sNDA Submission	06 Mar
Safety Update Submitted to FDA	29 Mar 2019
Approval	15 May



RTOR: Two different sNDA experiences

	Kisqali	Venclexta
Number of pivotal studies	2	1
Study Submission	CDISC	CDISC+non-CDISC
RTOR considered?	Requested by FDA after top line data availability	Planned at risk prior to top line data availability
RTOR data package	SDTM & key ADaM (without define.xml)	Full CRT package
Regular TC with FDA?	Yes	No
Information Requests during RTOR	Yes	Yes

Challenges

- Kisqali:
 - Lack of RTOR knowledge
 - Answering Information Requests (IR) whilst finalizing define.xml
- Venclexta
 - Risk taking in RTOR front-loading
 - Learning CDISC deliverables e.g. ADaM, conformance checking
- Common
 - Working on multiple priorities
 - Late changes to analyses



Opportunities

- Kisqali:
 - Early confirmation of right approach
- Venclexta:
 - Lack of substantial IRs → related to structure/content submitted?
- Common
 - Educating stakeholders about what we do
 - One of the first RTOR pilots → shared experiences with others



Recommendations

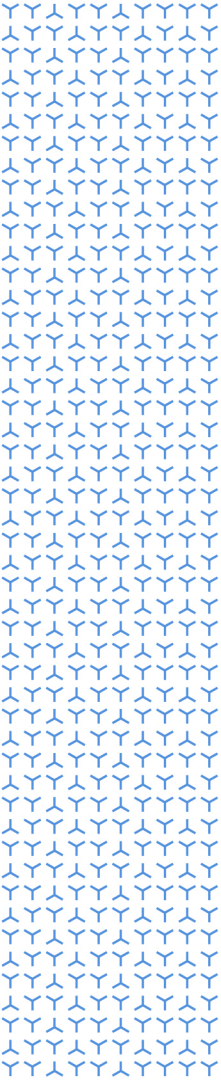
- Be eSubmission ready at DBL
- Explain to stakeholders what is involved
- Freeze planned analysis 1 month before DBL
- Plan resources ahead of time
- Consider de-prioritization of other deliverables



References



- <https://www.fda.gov/about-fda/oncology-center-excellence/real-time-oncology-review-pilot-program>
- <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-expands-ribociclib-indication-hr-positive-her2-negative-advanced-or-metastatic-breast-cancer>
- <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-venetoclax-cll-and-sll>



Thank you

***Doing now what patients need
next***

