

PADO Portfolio Staging

- The pediatric market is too small to support a large product development portfolio.
- We suggest staging the PADO list to focus supplier's resources.
- This structured approach will accelerate the time to market for all products and distribute efforts across suppliers.

Staging Development of PADO Priorities: Decision Tools

- CHAI has drafted of a weighted Pugh decision matrix.
 - A semi-quantitative technique used to rank assets against multi-dimensional options.
 - Employs an algorithm that combines the Pugh criteria scores and weights, time for collecting clinical data sufficient to launch at-risk product development, product development, and regulatory reviews.
- Prioritizes product development against a set of criteria related to clinical value, impact across weight bands, and market size.
- The results complements the output from PADO, but allows us to stage supplier product development.

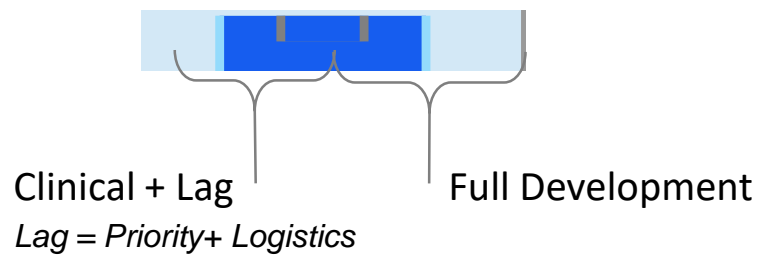
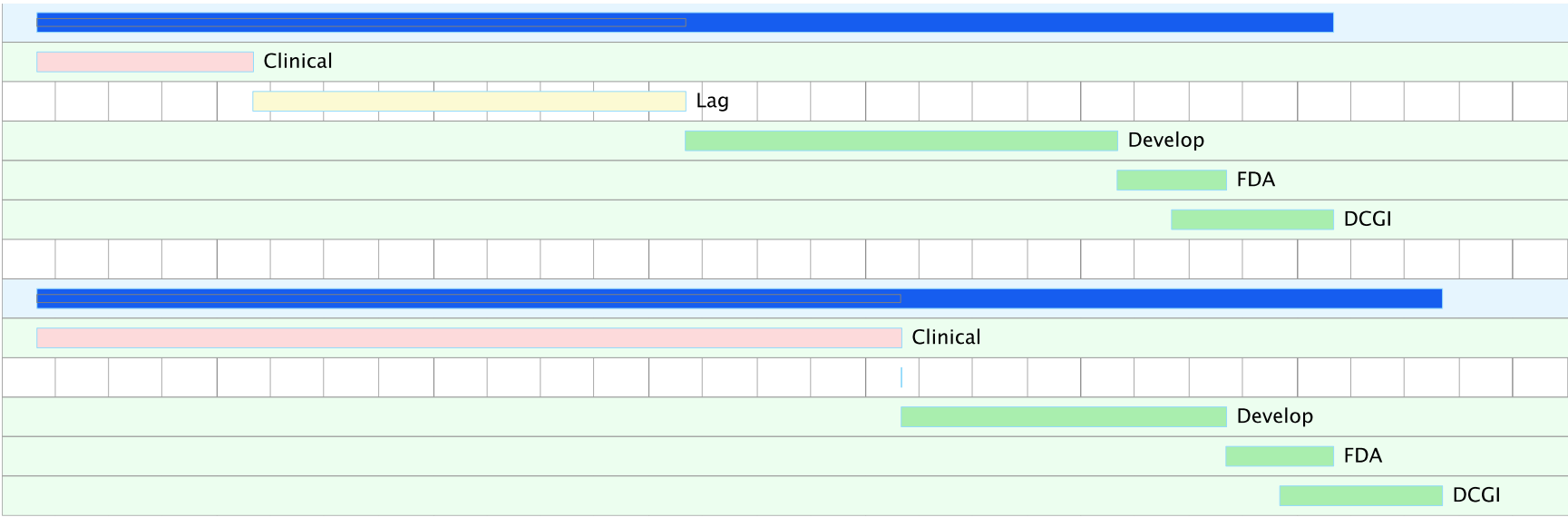
Staging Criteria

Criteria	Scores and Weights	Max = 5	Mid =2	Min = 1	Weight
1	Number of 1L patients that would transition to this	>50%	20% - 50%	<20%	3
2	Tolerability (e.g. ease of admin, pill burden, doses/day, taste/palatability, side effects that could affect adherence)	High	Moderate	Low	3
3	FDC is a complete regimen	Yes	No	N/A	2
4	Number of formulations across weight bands	1	2	3+	2
5	Number of 2L patients that would transition to this	>50%	20% - 50%	<20%	2
6	Harmonized with Adult API portfolio	Full	Partial	No	2
7	Coverage of weight bands (clinical evidence across weight bands)	All 6	4	2	1
8	Works in neonates	Yes	Unknown	No	1
9	<i>DDIs (TB)</i>	<i>None</i>	<i>Double Dose</i>	<i>Prohibits use</i>	<i>1</i>
?	<i>TBD</i>	<i>?</i>	<i>?</i>	<i>?</i>	<i>?</i>

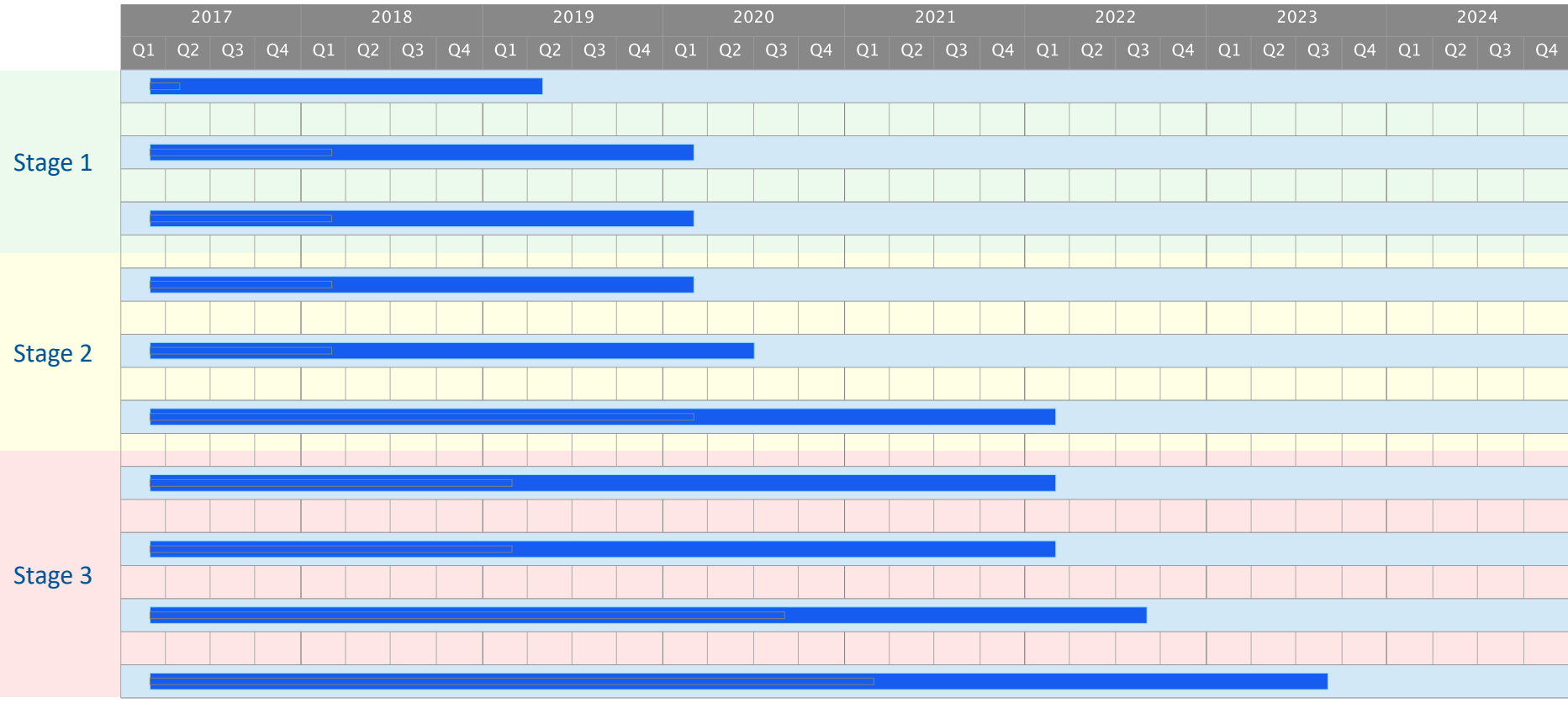
Integrating Additional Staging Parameters

Staging Concepts	Details
Priority Score	See previous slide
Clinical Development	Estimate on time to generate sufficient clinical evidence to launch generic product development
Development Status	A tiered lag based on the priority of those products not currently under development by a generic manufacturer
Development Duration	Cumulative duration to FDA Tentative Approval

Gantt chart key



Pediatric Portfolio Staging - A Priori



Timelines based on March 2017 analysis

Next Steps

- Finalization of criteria and scoring through face to face meetings with partners:
 - CROI – research toolkit meeting
 - AMDS
- Allows us to gather a wide range of input from clinical research groups and for programmatic aspects.
- Goal: Finalize Staged PADO list by IAS2018, July 2018