



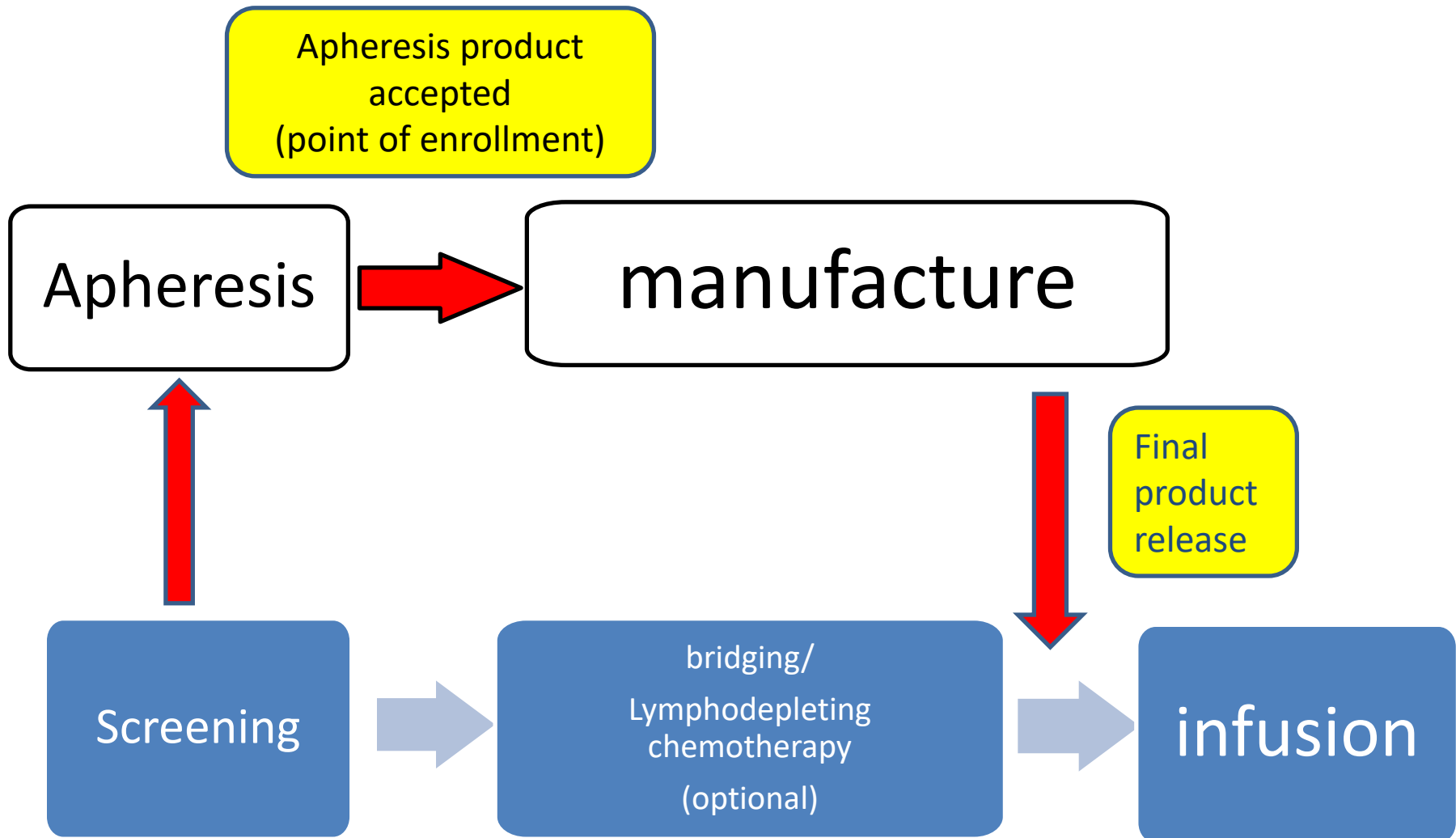
THE FORUM
For Collaborative ResearchSM

Specific Topics Panels: Panel 3 - Data Quality in Outcome Assessments

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Berkeley Public
Health

Study flow: treatment phase



Subject disposition

Screened	107
Not meet eligibility criteria	12
Apheresis product not accepted at manufacturing facility	1
Death	2
Screening date after data cutoff	4
Enrolled	88 (100%)
Manufacturing failure	8* (9%)
Death	9*(10%)
Adverse event	2 (2%)
Infusion pending	4 (5%)
Full analysis set	68
Subjects treated with products manufactured in Germany	5
Efficacy analysis set	63

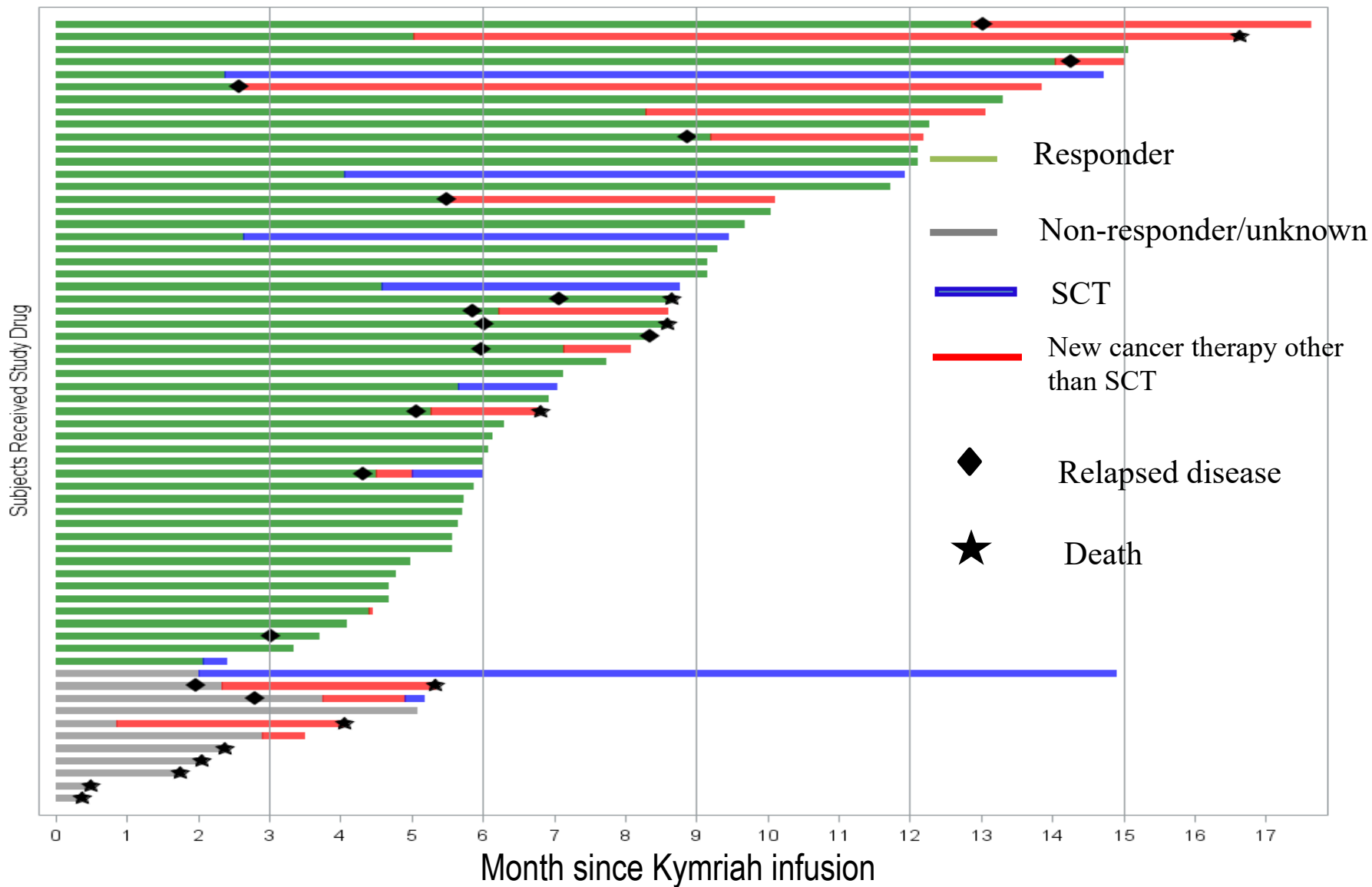
* 3 subjects counted twice, they died and their product did not successfully manufactured.

Efficacy results based on different analysis population

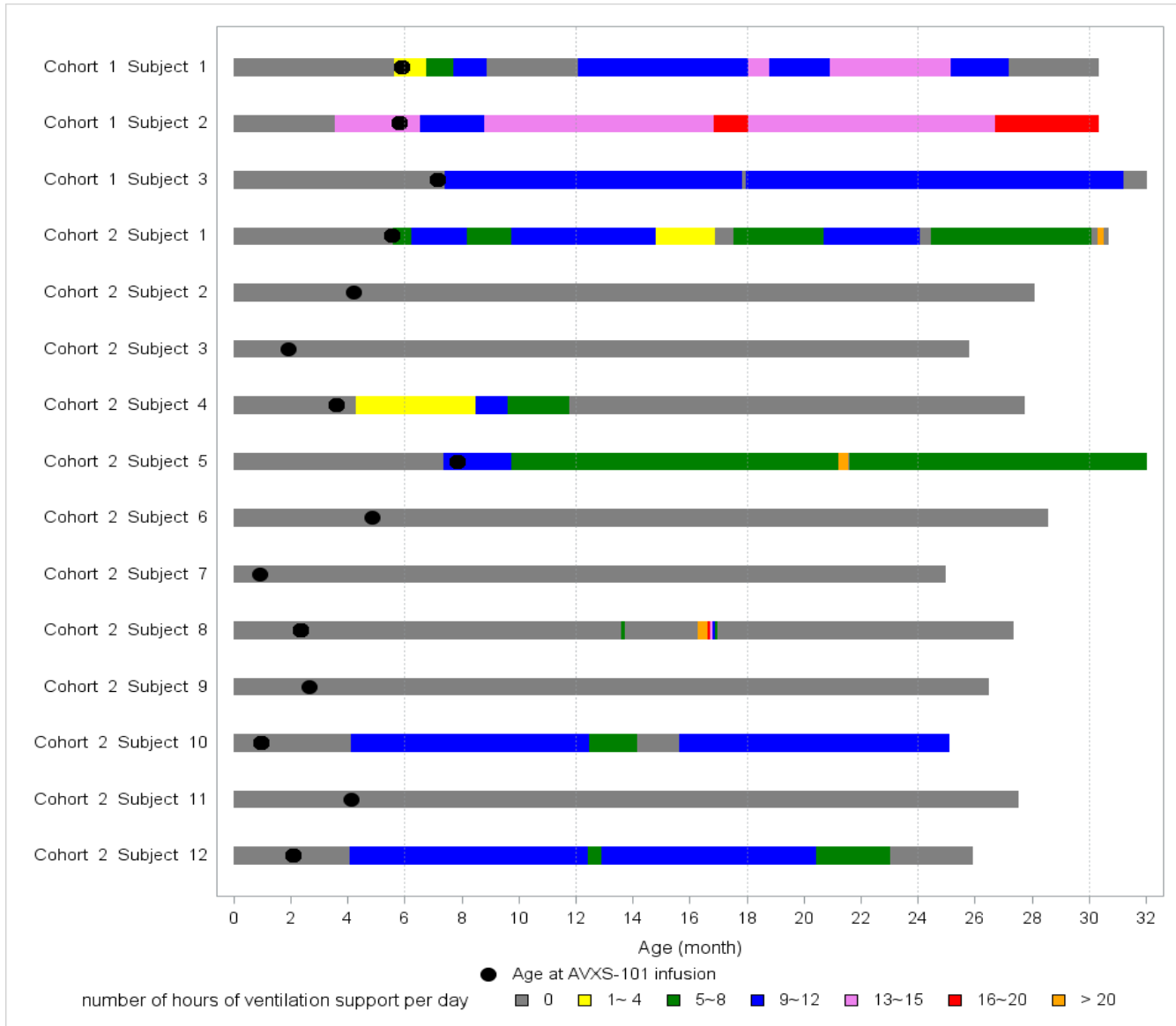
	Enrolled Set (n=88)	Modified Enrolled Set* (n=78)	Efficacy analysis Set (n=63)
ORR (95% CI)	59.1% (48.1, 69.5)	66.7% (55.1, 76.9)	82.5% (70.9, 91.0)
CR	45.5%	54.8%	63%
CRi	13.6%	16.4%	19%

* subjects who were enrolled and their apheresis products were accepted at the U.S. facility.

Overall Treatment Experience for each subject



Ventilation Support Hours for each subject



Developmental Milestones Achieved for each subject

