the potential to produce long-term OS gains over standard of care with docetaxel (doc). Robust estimates of mean OS are needed to understand long-term treatment benefit and to support health technology assessment. We developed a response-based modeling approach to extrapolate OS beyond observed clinical trial data for patients with NSCLC treated with nivo.

Materials and Methods: Data from three prospective clinical trials (CheckMate 003, 017, and 063) were used to estimate OS curves for patients with advanced NSCLC treated with second- or third-line nivo. Long-term OS beyond end-of-trial was projected via developed parametric curves and cancer registry data with longer follow-up, conditional on the RECIST response (complete/partial response [CR/PR], stable disease [SD], or progressive disease/non-evaluable response [PD/NE]) at two landmark points (6 or 12 months [mo]). For patients with CR/PR, three alternative nivo treatment effect durations (0, 5, or 10 years [y] beyond the trial period) were modeled. Mean OS (life expectancy) was calculated based on a weighted average of response-based curves. The goodness of fit and clinical validity of survival extrapolation were also assessed.

Table: Life expectancy estimates

	Stratification								
	At trial initiation			At time of response measurement					
				At 6 months			At 12 months		
Duration of nivo effect beyond trial, yr	0	5	10	0	5	10	0	5	10
Mean OS (life expectancy), mo									
Patients treated with nivo	20	24	26	19	22	23	17	19	20
Patients treated with doc	9	9	9	9	9	9	9	9	9
Survival gains (nivo vs doc)	11	15	17	10	13	14	8	10	11
CR/PR	59	82	92	47	64	72	34	46	52
SD	18	18	18	17	17	17	16	16	16
PD/NE	8	8	8	10	10	10	11	11	11

Results: Results from the long-term OS extrapolation are summarized in the table. Life expectancy for patients treated with nivo ranged from 17 to 26 mo, compared with 9 mo for patients treated with doc (CheckMate 017 comparator). When stratified by response, life expectancy with nivo was 34−92 mo, 16−18 mo, and 8−11 mo, respectively, for patients with CR/PR, SD, and PD/NE. For comparison, a simple parametric extrapolation of trial data without stratifying by response suggested a life expectancy of 14 mo for patients treated with nivo.

Conclusions: In light of immature survival data from clinical trials, a response-based modeling approach incorporating response status at a landmark avoids potential immortal time bias and improves the estimation of life expectancy for previously treated patients with advanced NSCLC treated with nivo. These methods may improve our understanding of the clinical and economic benefits of immuno-oncology agents in metastatic cancer.

Conflict of interest: *Ownership: J.R. Penrod and H. Dastani have stock ownership in Bristol-Myers Squibb. Other Substantive Relationships: J.R. Penrod, Y. Yuan, and H. Dastani are employees of Bristol-Myers Squibb; J. Thornton Snider, A. Sexton Ward, E. van Eijndhoven, and A. Chandra are employees of Precision Health Economics, which received consulting payments from Bristol-Myers Squibb for this work; A. Chandra is a professor at Harvard University, which was not involved in the research in any way, and serves on the Congressional Budget Office's Panel of Health Advisors.*

1330 POSTER

Comparative efficacy and safety of nivolumab (nivo) vs relevant treatments (txs) in pretreated non-squamous (NSQ) advanced non-small cell lung cancer (aNSCLC): Results from a systematic literature review (SLR) and indirect treatment comparisons (ITCs) of randomized controlled trials (RCTs)

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Background: CheckMate (CM) 057, a global, randomized, open-label, phase 3 trial, evaluated the efficacy and safety of nivo vs docetaxel (doc) in second- and third-line (2L/3L) NSQ aNSCLC patients (pts). Nivo is approved in the US and the EU in pretreated aNSCLC. We present results from an ITC against relevant txs not included in CM 057. ITCs are a methodology used to provide exploratory relative efficacy and safety estimates across txs linked through common comparators.

Methods: An SLR of efficacy and safety data from RCTs (January 2000 to October 2015) assessing txs in the 2L/3L aNSCLC setting was conducted. When >1 RCT was available for a tx pair, data were summarized using a meta-analysis random effects approach. Separate ITCs were conducted (using the Bucher method) based on: (1) results from intent-to-treat (ITT) populations that included 2L/3L NSQ (and potentially SQ) pts; (2) RCTs reporting NSQ subgroup results. Overall survival (OS) data were summarized as hazard ratios (HRs) and binary data as risk ratios (RRs). Analyses were performed using both constant and time-varying HRs.

Results: RCT data were available for pemetrexed (pem), erlotinib (erl), gefitinib (gef), ramucirumab (ram) + doc, nintedanib (nin) + doc, and best supportive care (BSC). Data from CM 057 and ITC results based on ITT evidence are reported (table). Further analyses based on an updated SLR incorporating additional tx comparators are ongoing.

Table. Nivo vs comparators in 2L/3L NSQ aNSCLC based on ITT evidence from relevant RCTs

Comparator	No. of RCTs [a]	OS, HR (95% CI)	PFS, HR (95% CI)	ORR, RR (95% CI)	DDTAEs [b], RR (95% CI)
Doc [c]	1	0.73 (0.59−0.89)	0.92 (0.77−1.11)	1.55 (1.05−2.27)	0.33 (0.18−0.59)
Pem [d]	4−8	0.71 (0.56−0.91)	0.86 (0.66−1.11)	1.33 (0.80−2.22)	0.44 (0.10−1.87)
Erl [d]	3−11	0.69 (0.53−0.91)	0.78 (0.60−1.02)	3.26 (0.67−16.00)	0.33 (0.08−1.34)
Gef [d]	5−15	0.71 (0.57−0.89)	0.95 (0.76−1.19)	0.98 (0.54−1.77)	0.62 (0.32−1.18)
Ram+doc [d]	2−3	0.85 (0.66−1.09)	1.20 (0.97−1.49)	0.93 (0.59−1.45)	0.19 (0.10−0.38)
Nin+doc [d]	2	0.78 (0.61−0.98)	1.17 (0.92−1.48)	1.17 (0.60−2.27)	0.31 (0.17−0.58)
BSC	3−5	0.43 (0.30−0.62)	0.44 (0.32−0.60)	NA	1.07 (0.17−6.82)

DDTAEs, discontinuation due to tx-related adverse events; NA, not available; PFS, progression-free survival; ORR, objective response rate.

[a] No. of RCTs in the ITC can vary by endpoint.

[b] Any grade AEs.

[c] Direct evidence from CM 057 primary analysis (database lock: Mar 18, 2015).

[d] NSQ-only estimates were available and broadly similar to ITT evidence (to be presented).

Conclusions: ITC evidence suggests that nivo generally improved OS relative to relevant 2L/3L treatments for NSQ aNSCLC (except ram + doc; CI included no effect). CIs for ITC estimates for PFS and ORR generally included no effect. ITC estimates of DDTAEs vs active tx comparators often favored nivo and were statistically significant for chemo-containing regimens (except pem). Limitations include differences in study design and pt populations across RCTs.

Conflict of interest: *Ownership: J.R. Penrod, D. Healey, and B. Korytowsky have stock ownership in Bristol-Myers Squibb. Advisory Board: M. Reck is an advisory board member for Hoffman-La Roche, Lilly, MSD, BMS, AstraZeneca, Boehringer-Ingelheim, Pfizer, and Novartis. Other Substantive Relationships: J.R. Penrod, C. Makris, D. Healey, and B. Korytowsky are employees of Bristol-Myers Squibb; A. Shrestha, K. Bognar, E. van Eijndhoven, S. Cope, and J. Vanderpuye-Orgle are employees of Precision Health Economics, which received consulting fees from BMS for this work.*

1331 POSTER

Comparative efficacy and safety of nivolumab (nivo) vs relevant treatments (txs) in pretreated squamous (SQ) advanced non-small cell lung cancer (aNSCLC): Results from a systematic literature review (SLR) and indirect treatment comparisons (ITCs) of randomized controlled trials (RCTs)

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Background: CheckMate (CM) 017, a global, randomized, open-label, phase 3 trial, evaluated the efficacy and safety of nivo vs docetaxel (doc) in second-line (2L) SQ aNSCLC patients (pts). Nivo is approved in the US and the EU in pretreated aNSCLC. Here we present results of an ITC against relevant txs not included in CM 017. ITCs are a methodology used to provide exploratory relative efficacy and safety estimates across txs linked through common comparators.