第3部　品質に関する文書
（該当なし）

第4部　非臨床試験報告書
（該当なし）

第5部　臨床試験報告書

5.2　臨床試験一覧表

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.2	臨床試験一覧表	-	-	-	-	-	-

5.3　臨床試験報告書
5.3.1　生物薬剤学試験報告書
5.3.1.1　バイオアベイラビリティ（BA）試験報告書
（該当なし）

5.3.1.2　比較BA試験及び生物学的同等性（BE）試験報告書
（該当なし）

5.3.1.3　*In Vitro-In Vivo* の関連を検討した試験報告書
（該当なし）

5.3.1.4　生物学的及び理化学的分析法検討報告書

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.1.4-1	Validation Report Addendum 13, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-

	Validation Report Addendum 14, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay					
	Validation Report Addendum 15, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay					
	Validation Report Addendum 16, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay					
	Validation Report Addendum 17, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay					
	Validation Report Addendum 18, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay					
	Validation Report Addendum 19, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay					
	Validation Report Addendum 20, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay					
	Validation Report Addendum 20 Amendment 1, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay					

	Validation Report Addendum 21, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay						
	Validation Report Addendum 22, Quantitative Determination of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay						
	Validation Report Addendum 23, Validation Report for the Quantitation of BMS-936558 in Human Serum by Electrochemiluminescent (ECL) Assay from Study SUW13						
5.3.1.4-2	Validation of an Analytical Method for Quantitative Determination of BMS-936558 in Human Serum by an Electrochemiluminescent (ECL)	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-
	Validation of an Analytical Method for Quantitative Determination of BMS-936558 in Human Serum by an Electrochemiluminescent (ECL), Method Validation Report Addendum 01						
	Validation of an Analytical Method for Quantitative Determination of BMS-936558 in Human Serum by an Electrochemiluminescent (ECL), Method Validation Report Addendum 02						
5.3.1.4-3	Method Validation Report Addendum 16, Validation of an ELISA Method for the Quantitation of BMS-734016 in Human Serum	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-
	Validation Report Addendum 17, Validation of an ELISA Method for the Quantitation of BMS-734016 in Human Serum						
	Validation Report Addendum 18, Validation of an ELISA Method for the Quantitation of BMS-734016 in Human Serum						

	Validation Report Addendum 19, Validation of an ELISA Method for the Quantitation of BMS-734016 in Human Serum						
	Validation Report Addendum 20, Validation of an ELISA Method for the Quantitation of BMS-734016 in Human Serum						
	Validation Report Addendum 21, Validation of an ELISA Method for the Quantitation of BMS-734016 in Human Serum						
	Validation Report Addendum 22, Validation of an ELISA Method for the Quantitation of BMS-734016 in Human Serum						
	Method Validation Report Addendum 23, Validation of an ELISA Method for the Quantitation of BMS-734016 in Human Serum						
	Validation Report Addendum 24, Validation Report for the Quantitation of BMS-734016 in Human Serum by ELISA from Study NMP24						
5.3.1.4-4	Validation of an Analytical Method for Quantitative Determination of BMS-734016 in Human Serum by an Enzyme-Linked Immunosorbent Assay (ELISA)	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-
	Validation of an Analytical Method for Quantitative Determination of BMS-734016 in Human Serum by an Enzyme-Linked Immunosorbent Assay (ELISA), Method Validation Report Addendum 01, 12 Months Stability						
	Validation of an Analytical Method for Quantitative Determination of BMS-734016 in Human Serum by an Enzyme-Linked Immunosorbent Assay (ELISA), Method Validation Report Addendum 02, Selectivity						

	Validation of an Analytical Method for Quantitative Determination of BMS-734016 in Human Serum by an Enzyme-Linked Immunosorbent Assay (ELISA) , Method Validation Report Addendum 03						
5.3.1.4-5	Method Validation Report Addendum 9, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-
	Method Validation Report Addendum 10, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum						
	Method Validation Report Addendum 11, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum						
	Method Validation Report Addendum 12, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum						
	Method Validation Report Addendum 13, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum						

	Method Validation Report Addendum 14, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum					
	Method Validation Report Addendum 15, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum					
	Method Validation Report Addendum 16, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum					
	Method Validation Report Addendum 17, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum					
	Method Validation Report Addendum 18, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum					
	Method Validation Report Addendum 19, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum					

	Method Validation Report Addendum 20, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum						
	Method Validation Report Addendum 21, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum						
	Method Validation Report Addendum 22, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum						
	Method Validation Report Addendum 23, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Disease State Human Serum						
5.3.1.4-6	Validation of an Electrochemiluminescence (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Human Serum	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-
	Validation of an Electrochemiluminescence (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Human Serum, METHOD VALIDATION REPORT ADDENDUM 01						
	Validation of an Electrochemiluminescence (ECL) Immunoassay for the Detection of Anti-BMS-936558 Antibodies in Human Serum, METHOD VALIDATION REPORT ADDENDUM 02						

5.3.1.4-7	Method Validation Report Addendum 10, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-734016 Antibodies in Human Serum	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-
	Validation Report Addendum 11, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-734016 Antibodies in Human Serum						
	Method Validation Report Addendum 12, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-734016 Antibodies in Human Serum						
	Method Validation Report Addendum 13, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-734016 Antibodies in Human Serum						
	Method Validation Report Addendum 14, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-734016 Antibodies in Human Serum						
	Method Validation Report Addendum 15, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-734016 Antibodies in Human Serum						
	Method Validation Report Addendum 16, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-734016 Antibodies in Human Serum						
	Method Validation Report Addendum 17, Validation of an Electrochemiluminescent (ECL) Immunoassay for the Detection of Anti-BMS-734016 Antibodies in Human Serum						

5.3.1.4-8	Validation of Bridging Electrochemiluminescence (ECL) Assay for the Detection of Anti-BMS-734016 Antibodies in Human Serum Validation of Bridging Electrochemiluminescence (ECL) Assay for the Detection of Anti-BMS-734016 Antibodies in Human Serum, Method Validation Report Addendum 01	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-
5.3.1.4-9	Validation of a Cell-Based Functional Assay for the characterization of Neutralizing Antibodies against BMS-936558 in human serum Validation of a cell-based functional assay for the Characterization of Neutralizing Antibodies against BMS-936558 in Human Serum, METHOD VALIDATION REPORT ADDENDUM 01	[redacted]	20[redacted]年[redacted]月	海外	-	評価	-

5.3.2 ヒト生体試料を用いた薬物動態関連の試験報告書

5.3.2.1 血漿蛋白結合試験報告書

（該当なし）

5.3.2.2 肝代謝及び薬物相互作用試験報告書

（該当なし）

5.3.2.3 他のヒト生体試料を用いた試験報告書

（該当なし）

5.3.3 臨床薬物動態（PK）試験報告書

5.3.3.1 健康被験者におけるPK及び初期忍容性試験報告書

（該当なし）

5.3.3.2 患者におけるPK及び初期忍容性試験報告書

（該当なし）

5.3.3.3 内因性要因を検討したPK試験報告書
（該当なし）

5.3.3.4 外因性要因を検討したPK試験報告書
（該当なし）

5.3.3.5 ポピュレーションPK試験報告書

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.3.5-1	POPULATION PHARMACOKINETICS OF NIVOLUMAB AND IPILIMUMAB WHEN ADMINISTERED IN COMBINATION IN SUBJECTS WITH UNRESECTABLE MALIGNANT PLEURAL MESOTHELIOMA AS FIRST-LINE THERAPY	Bristol-Myers Squibb	20[redacted]年[redacted]月	海外	社内資料	評価	有り
5.3.3.5-2	EXPOSURE-RESPONSE ANALYSIS OF EFFICACY AND SAFETY FOR NIVOLUMAB AND IPILIMUMAB WHEN ADMINISTERED IN COMBINATION IN SUBJECTS WITH UNRESECTABLE MALIGNANT PLEURAL MESOTHELIOMA AS FIRST-LINE THERAPY	Bristol-Myers Squibb	20[redacted]年[redacted]月	海外	社内資料	評価	有り

5.3.4 臨床薬力学（PD）試験報告書
5.3.4.1 健康被験者におけるPD試験及びPK/PD試験報告書
（該当なし）

5.3.4.2 患者におけるPD試験及びPK/PD試験報告書
（該当なし）

5.3.5 有効性及び安全性試験報告書
5.3.5.1 申請する適応症に関する比較対照試験報告書

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.5.1-1	Final Clinical Study Report for Study CA209743 A Phase III, Randomized, Open Label Trial of Nivolumab in combination with Ipilimumab versus Pemetrexed with Cisplatin or Carboplatin as First Line Therapy in unresectable Pleural Mesothelioma	Bristol-Myers Squibb	2016年11月～2020年1月（継続中）	国内／海外	社内資料	評価	有り

5.3.5.2 非対照試験報告書
（該当なし）

5.3.5.3 複数の試験成績を併せて解析した報告書
（該当なし）

5.3.5.4 その他の試験報告書

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.5.4-1	Summary of Clinical Safety 1L MPM 743 2020 Appendices	Bristol-Myers Squibb	-	-	社内資料	-	-

5.3.6 市販後の使用経験に関する報告書

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.6-1	新医療用医薬品に関する安全性定期報告書（ニボルマブ）	-	2019年7月～2020年1月	-	社内資料	参考	-
5.3.6-2	6-Month addendum report（ニボルマブ）	-	2019年7月～2020年1月	-	社内資料	参考	-
5.3.6-3	IPILIMUMAB Injection for Intravenous Infusion 1-YEAR PERIODIC BENEFIT RISK EVALUATION REPORT（PBRER）#10	-	2019年3月～2020年3月	-	社内資料	参考	-

5.3.6-4	新医療用医薬品に関する安全性定期報告書（イピリムマブ）	-	2019年9月～2020年3月	-	社内資料	参考	-

5.3.7 患者データ一覧表及び症例記録

5.3.7.1 主要な臨床試験の症例一覧表

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.7.1	主要な臨床試験の症例一覧表	-	-	-	-	-	-

5.3.7.2 有害事象発現症例一覧表

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.7.2	有害事象発現症例一覧表	-	-	-	-	-	-

5.3.7.3 重篤な有害事象発現症例一覧表

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.7.3	重篤な有害事象発現症例一覧表	-	-	-	-	-	-

5.3.7.4 臨床検査値異常変動発現症例一覧表

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.7.4	臨床検査値異常変動発現症例一覧表	-	-	-	-	-	-

5.3.7.5 臨床検査値の変動図

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
5.3.7.5	臨床検査値の変動図	-	-	-	-	-	-

5.4 参考文献

添付資料番号	タイトル	著者	試験実施期間	実施場所国内/海外	掲載誌	評価/参考	申請電子データ有無
	「都道府県別にみた中皮腫による死亡数の年次推移（平成7年～30年）人口動態統計（確定数）」	厚生労働省	-	-	Available at: https://www.mhlw.go.jp/toukei/saikin/hw/jinkou/tokusyu/chuuhisyu18/dl/chuuhisyu.pdf	-	-
	Combination therapy with anti-CTLA-4 and anti-PD-1 leads to distinct immunologic changes in vivo	Das R, Verma R, Sznol M, et al	-	-	J Immunol. 2015; 194:950-9	-	-
	Final Clinical Study Report for Part1 of Study CA209227. An Open-Label, Randomized Phase 3 Trial of Nivolumab, or Nivolumab plus Ipilimumab, or Nivolumab plus Platinum Doublet Chemotherapy versus Platinum Doublet Chemotherapy in Subjects with Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC)	Bristol-Myers Squibb	-	-	社内資料	-	-
	Final Clinical Study Report for Study CA209025 (Part A). A Randomized, Open-Label, Phase 3 Study of Nivolumab (BMS-936558) versus Everolimus in Subjects with Advanced or Metastatic Clear-Cell Renal Cell Carcinoma Who Have Received Prior Anti-Angiogenic Therapy (CheckMate 025, CHECKpoint pathway and nivoluMAb clinical Trial Evaluation)	Bristol-Myers Squibb	-	-	社内資料	-	-

	Final Clinical Study Report for Study CA209214 (Part A). A Phase 3, Randomized, Open-Label Study of Nivolumab Combined with Ipilimumab Versus Sunitinib Monotherapy in Subjects with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma (CheckMate 214, CHECKpoint pathway and nivoluMAb clinical Trial Evaluation 214)	Bristol-Myers Squibb	-	-	社内資料	-	-
	Final Clinical Study Report for Study IFCT-1501 MAPS2. A randomized Phase II study evaluating efficacy and safety of 2nd or 3rd line treatment by nivolumab monotherapy or nivolumab plus ipilimumab, for unresectable malignant pleural mesothelioma (MPM) patients	Intergroupe francophone de Cancerologie Thoracique	-	-	社内資料	-	-
	Five-Year Survival with Combined Nivolumab and Ipilimumab in Advanced Melanoma	Larkin J, Chiarion-Sileni V, Gonzalez R, et al	-	-	N Engl J Med. 2019;381:1535-46	-	-
	Fundamental mechanisms of immune checkpoint blockade therapy	Wei SC, Duffy CR, Allison JP	-	-	Cancer Discov. 2018;8:1069-86	-	-
	Future trend of mesothelioma mortality in Japan based on a risk function	Myojin T, Azuma K, Okumura J, et al	-	-	Ind Health. 2012;50:197-204	-	-

	Guidance for Industry, Clinical trial endpoints for the approval of cancer drugs and biologics	-	-	-	U.S. Department of Health and Human Services, Food and Durg Administration, Oncology Center of Excellence, Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER). 2018	-	-
	In vitro characterization of the anti-PD-1 antibody nivolumab, BMS-936558, and in vivo toxicology in non-human primates	Wang C, Thudium KB, Han M, et al	-	-	Cancer Immunol Res. 2014;2:846-56	-	-
	Ipilimumab: a novel immunostimulatory monoclonal antibody for the treatment of cancer	Graziani G, Tentori L, Navarra P	-	-	Pharmacol Res. 2012;65:9-22	-	-
	Mesothelioma: a review	Mott FE	-	-	Ochsner J. 2012;12:70-9	-	-
	National survey of malignant mesothelioma and asbestos exposure in Japan	Gemba K, Fujimoto N, Kato K, et al	-	-	Cancer Sci. 2012;103:483-90	-	-
	NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), Malignant Pleural Mesothelioma Version 1. 2020	-	-	-	National Comprehensive Cancer Network. 2019	-	-
	Negative co-stimulation constrains T cell differentiation by imposing boundaries on possible cell states	Wei SC, Sharma R, Anang NAS, et al	-	-	Immunity. 2019;50:1084-98	-	-

	Nivolumab plus ipilimumab as first-line treatment for advanced non-small-cell lung cancer (CheckMate 012): results of an open-label, phase 1, multicohort study	Hellmann MD, Rizvi NA, Goldman JW, et al	-	-	Lancet Oncol. 2017;18:31-41	-	-
	Nivolumab plus Ipilimumab in Advanced Non–Small-Cell Lung Cancer	Hellmann MD, Paz‐Ares L, Bernabe Caro R, et al	-	-	N Engl J Med. 2019;381:2020-31	-	-
	PD-1 and PD-1 ligands: from discovery to clinical application	Okazaki T, Honjo T	-	-	Int Immunol. 2007;19:813-24	-	-
	Pemetrexed plus cisplatin or pemetrexed plus carboplatin for chemonaive patients with malignant pleural mesothelioma: results of the International Expanded Access Program	Santoro A, O'Brien ME, Stahel RA, et al	-	-	J Thorac Oncol. 2008;3:756-63	-	-
	Phase I study of single-agent anti-programmed death-1 (MDX-1106) in refractory solid tumors: safety, clinical activity, pharmacodynamics, and immunologic correlates	Brahmer JR, Drake CG, Wollner I, et al	-	-	J Clin Oncol. 2010;28:3167-75	-	-
	Phase II study of pemetrexed in combination with carboplatin in patients with malignant pleural mesothelioma (MPM)	Castagneto B, Botta M, Aitini E, et al	-	-	Ann Oncol. 2008;19:370-3	-	-
	Phase II study of pemetrexed plus carboplatin in malignant pleural mesothelioma	Ceresoli GL, Zucali PA, Favaretto AG, et al	-	-	J Clin Oncol. 2006;24:1443-8	-	-
	Phase III study of pemetrexed in combination with cisplatin versus cisplatin alone in patients with malignant pleural mesothelioma	Vogelzang NJ, Rusthoven JJ, Symanowski J, et al	-	-	J Clin Oncol. 2003;21:2636-44	-	-
	Programmed cell death 1 ligand 1 and tumor-infiltrating CD8+ T lymphocytes are prognostic factors of human ovarian cancer	Hamanishi J, Mandai M, Iwasaki M, et al	-	-	Proc Natl Acad Sci U S A. 2007;104:3360-5	-	-

	Second line therapy in malignant pleural mesothelioma: A systematic review	Buikhuisen WA, Hiddinga BI, Baas P, et al	-	-	Lung Cancer. 2015;89:223-31	-	-
	The blockade of immune checkpoints in cancer immunotherapy	Pardoll DM	-	-	Nat Rev Cancer. 2012;12:252-64	-	-
	Treatment and survival analyses of malignant mesothelioma in Japan	Gemba K, Fujimoto N, Aoe K, et al	-	-	Acta Oncol. 2013;52:803-8	-	-
	オプジーボ®点滴静注20mg　オプジーボ®点滴静注100mg　オプジーボ®点滴静注240mg　医薬品添付文書　2020年9月改訂（第2版、用法変更、用量変更）	小野薬品工業株式会社	-	-	-	-	-
	がん情報サービス「がん登録・統計」（全国がん登録）；「全国がん罹患データ（2016年～2017年）」	国立がん研究センター	-	-	Available at: https://ganjoho.jp/data/reg_stat/statistics/dl/cancer_incidenceNCR(2016-2017).xls	-	-
	平成29年患者調査	厚生労働省大臣官房統計情報部編	-	-	Available at: https://www.e-stat.go.jp/stat-search/files?page=1&layout=datalist&toukei=00450022&tstat=000001031167&cycle=7&tclass1=000001124800&tclass2=000001124803&stat_infid=000031790842	-	-

	悪性胸膜中皮腫診療ガイドライン　2018年版	日本肺癌学会編	-	-	Available at: https://www.haigan.gr.jp/guideline/2018/2/0/180200000100.html	-	-
	平成30年度石綿健康被害救済制度運用に係る統計資料	独立行政法人環境再生保全機構石綿健康被害救済部編	-	-	Available at: https://www.erca.go.jp/asbestos/relief/uketsuke/pdf/toukei_30.pdf	-	-