1.12. 添付資料一覧

1.12.1. 添付資料一覧

第3部（品質に関する文書）						
添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
3	Dabrafenib Capsules Quality	20[redacted]年[redacted]月～継続中	GlaxoSmithKline	海外	社内資料	評価
第4部（非臨床試験報告書）						
添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.1.1						
UH2008/00147/01	In vitro biochemical characterization of GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UP, RTP（米国）、GSK-Harlow, Stevenage（英国）、[redacted]（スコットランド）、[redacted]（スコットランド）	海外	社内資料	評価
UH2010/00028/02	In vitro biochemical activity of GSK2118436 against multiple BRAF mutant proteins at amino acid V600	20[redacted]年[redacted]月～20[redacted]年[redacted]月（20[redacted]年[redacted]月改訂）	GSK-UM（米国）	海外	社内資料	評価
2011N111729_00	Enzyme inhibition profiling for GSK2285403A and GSK2167542A: two active metabolites of BRAF inhibitor, GSK2118436A against 292 kinases from[redacted]	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（英国）	海外	社内資料	評価
2012N139510_00	Kinase profiling for GSK2118436A and its active metabolites, GSK2298683A, GSK2285403A and GSK2167542A, as well as GSK2794360A (PLX4032)	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（英国）	海外	社内資料	評価
2012N153146_00	Inhibition of mouse, rat and dog PERK kinase activity by GSK2118436A and its active metabolites as well as GSK2794360A (PLX4032)	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-RTP（米国）	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.1.1						
UH2008/00132/02	Characterization of cellular activity of GSK2118436A	20[redacted]年[redacted]月～20[redacted]年[redacted]月（20[redacted]年[redacted]月 改訂）	GSK-UP (米国)	海外	社内資料	評価
2011N116395_00	Cellular assays with GSK2118436A, GSK1120212B, and GSK2126458A as single agents and in combination with each other in BRAF V600E/K/D mutant melanoma cell lines	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UP (米国)	海外	社内資料	評価
2011N116394_00	Cellular assays with GSK2118436A, GSK1120212B, and GSK2126458A as a single agent and in combination in BRAF V600 mutant melanoma cell lines that acquired resistance to GSK2118436A mediated by NRAS or MEK mutations	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UP (米国)	海外	社内資料	評価
UH2008/00145/03	Efficacy of BRAF Inhibitor GSK2118436A in Various Mouse Xenograft Models of Human Cancer	20[redacted]年[redacted]月～20[redacted]年[redacted]月（20[redacted]年[redacted]月 改訂）	GSK-UP (米国)	海外	社内資料	評価
2011N120928_00	Evaluation of GSK2118436A (KN59) and GSK1120212B (KN45) in the A375P F11S Human Melanoma Xenograft Model	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (米国)	海外	社内資料	評価
UH2010/00045/02	In vitro and In Vivo Characterizations of GSK2285403, GSK2298683 and GSK2167542: Active Metabolites of B-Raf inhibitor, GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月（20[redacted]年[redacted]月 改訂）	GSK-UP, RTP (米国)、GSK-Harlow, Stevenage (英国)	海外	社内資料	評価
2013N178509_00	Evaluation of GSK2118436 and its metabolites, GSK2298683, GSK2285403 and GSK2167542 to inhibit human TGFBR1 (ALK5) kinase activity	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (英国)	海外	社内資料	評価
2012N147468_00	Cellular activity of GSK2118436A and its metabolites, GSK2298683A, GSK2285403A, and GSK2167542A, in BRAF V600E/K/D mutant melanoma cell lines	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UP (米国)	海外	社内資料	評価
UH2009/00016/01	In vitro and Cell Based Activity of GSK2285403A, a Metabolite of GSK2118436A	20[redacted]年[redacted]月～20[redacted]年[redacted]月（20[redacted]年[redacted]月 改訂）	GSK-UP, RTP (米国)、GSK-Harlow, Stevenage (英国)	海外	社内資料	評価
2012N132871_01	Evaluation of GSK2118436A (KN59) Combined with GSK1120212B (KN45) in the A375P F11S Human Melanoma Xenograft Model	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (米国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.1.1						
2012N139280_00	Efficacy of MEK inhibitor GSK1120212B and BRAF inhibitor GSK2118436A, administered separately or in combination, in mouse tumor xenograft models of human melanoma	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UP（米国）	海外	社内資料	評価
2012N152372_01	Anti-tumor effect of BRAF (GSK2118436) and MEK (GSK1120212) inhibitors, alone or in combination, in a minimal disease model of BRAF mutant human melanoma (xenograft) in mice	20[redacted]年[redacted]月～20[redacted]年[redacted]月（20[redacted]年[redacted]月改訂）	GSK-UP（米国）	海外	社内資料	評価
4.2.1.2						
UH2009/00010/00	Biochemical screening of GSK2118436 in the eXP panel of receptors, ion channels and various proteins	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UP（米国）	海外	社内資料	評価
UH2008/00132/02	Characterization of cellular activity of GSK2118436A	20[redacted]年[redacted]月～20[redacted]年[redacted]月（20[redacted]年[redacted]月改訂）	GSK-UP（米国）	海外	社内資料	評価
4.2.1.3						
VD2008/00869/00	Acute Neurobehavioural Effects Following Oral Administration in the Conscious Crl:CD (SD) Rat	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（フランス）	海外	社内資料	評価
FD2008/00376/00	Effect on hERG Tail Current Recorded from Stably Transfected HEK-293 Cells	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-Ware, Frythe（英国）	海外	社内資料	評価
UH2010/00045/02	In vitro and In Vivo Characterizations of GSK2285403, GSK2298683 and GSK2167542: Active Metabolites of B-Raf inhibitor, GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-UP, RTP (米国)、GSK-Harlow, Stevenage (英国)	海外	社内資料	評価
UD2009/00043/00	Preclinical Test of GSK2118436A for QT Prolongation and TdP Risk Using the Rabbit Left Ventricular Wedge Preparation	20[redacted]年[redacted]月	GSK-UP（米国）	海外	社内資料	評価
CD2008/01717/00	Investigative Study of the Acute Effects on Cardiovascular Function Following Single Oral Administration in the Crl:CD (SD) Rat	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM（米国）	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.1.3						
CD2008/01280/00	Acute Effects on Cardiovascular Function Following Oral Administration in the Conscious Beagle Dog	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2008/01279/00	Acute Effects on Respiratory Function Following Oral Administration in the Conscious CRL:CD (SD) Rat	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2013N159876_00	GPCR-EP1, EP2, EP3 and EP4 profiling for GSK2118436A and its active metabolites, GSK2298683A (M4), GSK2285403A (M7) and GSK2167542A (M8), as well as GSK2794360A (PLX4032)	20[redacted]年[redacted]月	[redacted](ドイツ)	海外	社内資料	評価
2013N160976_00	The effects of GSK1120212B (trametinib) and GSK2118436A (dabrafenib) and its metabolites (GSK2285403A, GSK2167542A and GSK2298683A) on cytokine induction from human peripheral blood mononuclear cells in-vitro	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-Stevenage (英国)	海外	社内資料	評価
2012N153974_00	GSK1120212, GSK2118436A, GSK2285403, GSK2298683, and GSK2167542: In vitro evaluation of the potential for induction of cytokines in human whole blood	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
4.2.2.1						
2010N111293_00	The Abbreviated Validation of a Method for the Determination of GSK2118436 and its Metabolites (GSK2285403 and GSK2167542) in Mouse Plasma (range 10 to 10000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N109658_00	The validation of a method for the determination of GSK2298683 in mouse plasma (range 5 to 5000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2008/01640/00	The Abbreviated Validation of a Method for the Determination of GSK2118436 in Rat Plasma (range 5 to 5000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00412/00	The Abbreviated Validation of a Method for the Determination of GSK2118436 and its Metabolite (GSK2285403) in Rat Plasma (range 1 to 1000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.2.1						
CD2009/00950/00	The Abbreviated Validation of a Method for the Determination of GSK2118436, and its Metabolites (GSK2285403 and GSK2167542) in Rat Plasma (range 10 to 10000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2010/00021/00	The Abbreviated Validation of a Method for the Determination of GSK2298683 (range 5 to 5000 ng/mL) in Rat Plasma Using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2008/01669/00	The Validation of a Method for the Determination of GSK2118436 in Dog Plasma (range 5 to 5000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00411/00	The Validation of a Method for the Determination of GSK2118436 and its Metabolite (GSK2285403) in Dog Plasma (range 1 to 1000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00897/00	The Validation of a Method for the Determination of GSK2118436, and its Metabolites (GSK2285403 and GSK2167542) in Dog Plasma (range 10 to 10000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00902/00	The Validation of a Method for the Determination of GSK2118436 and its Metabolites (GSK2285403 and GSK2167542) in Dog Plasma (range 10 to 10000 ng/mL) using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00953/01	The Validation of a Method for the Determination of GSK2298683 (range 5 to 5000 ng/mL) in Dog Plasma using UHPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-Ware (英国) GSK-UM (米国) GSK-RTP (米国) GSK-Verona (イタリア)	海外	社内資料	評価
4.2.2.2						
UH2008/00115/03	Preliminary Drug Metabolism and Pharmacokinetics of GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-Collegeville (米国) [redacted] Services (中華民国) [redacted] (米国)	海外	社内資料	参考

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.2.2						
CD2009/00799/00	GSK2118436B: Single-Dose Oral Toxicokinetic and Tolerability Study in Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2011N126179_00	The Assessment of the Systemic Exposure of GSK2118436 and its Metabolites GSK2298683 (M4), GSK2285403 (M7) and GSK2167542 (M8) following a Single Oral Administration of GSK2118436B Suspension at 20 mg/kg to Male Crl:CD(SD) Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-RTP (米国)	海外	社内資料	評価
CD2010/00052/00	GSK2118436A: A 13 Week Oral Gavage Toxicity Study in the Rat Followed by a 4-week Recovery	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted](カナダ)	海外	社内資料	評価
CD2008/01638/00	An Evaluation of the Systemic Exposure of GSK2118436 Following Oral Administration of GSK2118436A (free base, micronized in capsule), GSK2118436B (mesylate salt in capsule or suspension) at 10 mg/kg in Fasted Male Beagle Dogs	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00595/00	An Evaluation of the Systemic Exposure of GSK2118436 and its Metabolite GSK2285403 (M7) following Oral Administration of Micronized GSK2118436B (Mesylate Salt) in Capsules at 10 mg/kg in Fasted Male Beagle Dogs	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2008/01503/02	GSK2118436A: 4-Week Oral Toxicity Study in Dogs Followed by a 2-Week Recovery Period	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
CD2010/00051/00	GSK2118436B: A 13 Week Twice Daily Oral Capsule Toxicity Study in the Beagle Dog Followed by a 4-Week Recovery	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted](カナダ)	海外	社内資料	評価
2011N112335_00	GSK1120212B and GSK2118436B: 4-Week Twice Daily Oral Toxicity Study in Dogs	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2010/00179/00	GSK1120212B: A 13 Week Oral Gavage Toxicity Study in the Beagle Dog with a 4 Week Recovery	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
4.2.2.3.						
RD2009/00091/00	Quantitative Tissue Distribution of Radioactivity Using Whole-Body Autoradiography Following a Single Oral Administration of [14C]GSK2118436 (10 mg/kg) to Partially Pigmented Male Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted](米国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.2.3						
2010N108408_00	Quantitative Tissue Distribution of Radioactivity Using Whole-Body Autoradiography Following a Single Oral Administration of [14C]GSK2118436 (10 mg/kg) to Partially Pigmented Female Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted](米国)	海外	社内資料	評価
RD2010/00439/00	An Evaluation of the Tissue Exposure and Spatial Distribution of GSK2118436 and its Metabolites GSK2298683 (M4), GSK2285403 (M7) and GSK2167542 (M8) Following 5 Days Repeat Oral Administration of GSK2118436A in Female Mice Bearing A375 F11 Tumor Xenograft using MALDI-IMS and LC-MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-RTP (米国)	海外	社内資料	評価
2011N112641_00	An Evaluation of Tissue and Systemic Exposure of GSK2118436 and its Metabolites GSK2298683 (M4), GSK2285403 (M7) and GSK2167542 (M8) Following 5 Days Repeat Oral Administration of GSK2118436A in Female Mice Bearing A375pF11s Tumor Xenografts	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2011N113766_00	A Positron Emission Tomography study to assess the CNS penetration of the Braf inhibitor [18F]GSK2118436 in the pig brain	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted](デンマーク)	海外	社内資料	評価
UH2008/00115/03	Preliminary Drug Metabolism and Pharmacokinetics of GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK Collegeville (米国) [redacted](米国)	海外	社内資料	参考
2011N129517_00	An Investigation of the in vitro Protein Binding of GSK2118436 and Its Circulating Metabolites GSK2298683 (M4), GSK2285403 (M7) and GSK2167542 (M8) in Male Human Plasma	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
UH2009/00085/00	Investigation of the In Vitro Plasma Protein Binding of GSK2298683B and GSK2167542A (M4 and M8 metabolites of GSK2118436) in Fresh Mouse, Rat, Dog and Human Plasma using Equilibrium Dialysis	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
UH2009/00043/00	GSK2285403A: Preliminary Investigation of the In Vitro Plasma Protein Binding in Mouse, Rat, Dog, Monkey and Human using Equilibrium Dialysis	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-Collegeville (米国)	海外	社内資料	評価
UH2009/00084/00	Preliminary Investigation of the In Vitro Blood to Plasma Partitioning of GSK2298683B and GSK2167542A (M4 and M8 Metabolites of GSK2118436) in Human, Dog, Rat and Mouse	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-Collegeville (米国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.2.3						
UH2009/00042/00	Preliminary Investigation of the In Vitro Blood to Plasma Partitioning of GSK2285403A in Human, Monkey, Dog, Rat and Mouse	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-Collegeville (米国)	海外	社内資料	評価
UD2010/00042/00	Assessment of possible P-glycoprotein (Pgp)-mediated efflux and intrinsic permeability of GSK2285403A, GSK2167542A and GSK2298683B, 3 known metabolites of GSK2118436, across MDR1-MDCKII cell monolayers	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	[redacted] (米国)	海外	社内資料	評価
2014N222543_00	In vitro evaluation of GSK2298683 as a substrate of OAT1and/or OAT3	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	[redacted] (日本)	国内	社内資料	評価
2014N204589_00	An in vitro investigation into the uptake of GSK2118436, GSK2285403, GSK2167542, and GSK2298683 in cryopreserved human hepatocytes and into cells singly overexpressing OATP1B1, OATP1B3 or OATP1A2	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2014N218314_00	An in vitro investigation into the uptake of GSK2118436, GSK2285403 and GSK2167542 into cells singly overexpressing OATP1A2	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00143/01	An In Vitro Investigation of the Inhibition by GSK2118436B of Xenobiotic Transport Via Human P-Glycoprotein, Heterologously Expressed in MDCKII Cells	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
2011N119324_01	An In Vitro Investigation of the Inhibition of Xenobiotic Transport Via Human P-Glycoprotein, Heterologously Expressed in MDCKII Cells by the Metabolites of GSK2118436: GSK2285403, GSK2298683 and GSK2167542	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
2011N112849_00	An In Vitro Investigation into the Inhibition by GSK2118436 of Xenobiotic Transport via Human Breast Cancer Resistance Protein Heterologously Expressed in MDCKII Cells	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2011N119323_00	An In Vitro Investigation into the Inhibition of Xenobiotic Transport via Human Breast Cancer Resistance Protein Heterologously Expressed in MDCKII Cells by the Metabolites of GSK2118436: GSK2285403, GSK2298683 & GSK2167542	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00116/00	An In Vitro Investigation into the Inhibition by GSK2118436 of Xenobiotic Transport via Human OATP1B1 and OATP1B3	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.2.3						
2010N110987_00	An In Vitro Investigation into the Inhibition by GSK2298683 of Xenobiotic Transport via Human OATP1B1 and OATP1B3	[redacted]	GSK-UM (米国)	海外	社内資料	評価
2010N110986_00	An In Vitro Investigation into the Inhibition by GSK2285403 of Xenobiotic Transport via Human OATP1B1 and OATP1B3	[redacted]	GSK-UM (米国)	海外	社内資料	評価
CD2010/00386/00	An In Vitro Investigation into the Inhibition by GSK2167542 of Xenobiotic Transport via Human OATP1B1 and OATP1B3	[redacted]	GSK-UM (米国)	海外	社内資料	評価
2012N131808_01	An In Vitro Investigation into the Inhibition by GSK2118436 and its circulating metabolites, GSK2298683, GSK2285403 and GSK2167542 of Xenobiotic Transport via Human OAT1 and OAT3	[redacted]	GSK-Ware (英国)	海外	社内資料	評価
2014N220059_01	In vitro evaluation of GSK2118436, GSK2285403, GSK2167542 and GSK2298683 as inhibitors of OCT2 transporter	[redacted]	[redacted] (日本)	国内	社内資料	評価
4.2.2.4						
CD2009/00471/00	An In Vitro Investigation of the Hepatic Metabolism of [14C]GSK2118436 in the Mouse, Rat, Female Rabbit, Dog, Cynomolgus Monkey and Human	[redacted]	GSK-UM (米国)	海外	社内資料	評価
CD2009/00061/00	An In Vitro Investigation of the Potential for GSK2118436 Bioactivation Following Incubation of [14C]GSK2118436 with Human Liver Microsomes	[redacted]	GSK-UM (米国)	海外	社内資料	評価
CD2009/00153/01	Investigation of Biliary metabolites of GSK2118436 following administration of [14C]GSK2118436 to the isolated perfused livers of male Sprague-Dawley rats.	[redacted]	GSK-UM (米国)	海外	社内資料	評価
CD2009/00144/00	A Preliminary Biotransformation Study to Investigate the Circulating Metabolites Following Single Oral Administration of 30 mg/kg [14C]GSK2118436 to Female Mice	[redacted]	GSK-UM (米国)	海外	社内資料	評価
2011N111703_00	Metabolism of GSK2118436 Following a Single Oral Administration (10 mg/kg) of [14C]GSK2118436 to Intact Male and Female and Bile Duct-Cannulated Male Rats	[redacted]	GSK-UM (米国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.2.4						
2011N126179_00	The Assessment of the Systemic Exposure of GSK2118436 and its Metabolites GSK2298683 (M4), GSK2285403 (M7) and GSK2167542 (M8) following a Single Oral Administration of GSK2118436B Suspension at 20 mg/kg to Male Crl:CD(SD) Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-RTP (米国)	海外	社内資料	評価
CD2010/00052/00	GSK2118436A: A 13 Week Oral Gavage Toxicity Study in the Rat Followed by a 4-week Recovery	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (カナダ)	海外	社内資料	評価
2011N111704_00	Metabolism of GSK2118436 in Male and Female Intact Dogs Following a Single Oral Administration of [14C]GSK2118436 at a Dose Level of 10 mg/kg	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2008/01503/02	GSK2118436A: 4-Week Oral Toxicity Study in Dogs Followed by a 2-Week Recovery Period	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
CD2009/00079/00	An In Vitro Investigation into the Human Oxidative Enzymology of GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2010/00233/01	An In Vitro Investigation into the Human Oxidative Enzymology of [14C]GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
2011N129873_00	A preliminary in vitro investigation into the human oxidative enzymology of GSK2167542, GSK2285403 and GSK2298683, the metabolites of GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2008/01428/00	An In Vitro Evaluation of the Effect of GSK2118436 on mRNA levels of Cytochrome P450 genes in Cultured Human Hepatocytes	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N110340_00	An In Vitro Investigation into the Inhibition of Human Cytochrome P450 Enzymes: CYP1A2, CYP2C9, CYP2C19 and CYP2D6 by GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
UH2008/00115/03	Preliminary Drug Metabolism and Pharmacokinetics of GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-Collegeville (米国) [redacted] (英国)	海外	社内資料	参考

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.2.4						
CD2009/00012/00	An In Vitro Investigation into the Inhibition of Human Cytochrome P450 Enzymes by GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N110991_00	An In vitro Investigation into the inhibition of Human Cytochrome P450 Enzymes by GSK2298683	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N111279_00	An In vitro Investigation into the inhibition of Human Cytochrome P450 Enzymes by GSK2285403	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N111291_01	An In vitro Investigation into the inhibition of Human Cytochrome P450 Enzymes by GSK2167542	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
4.2.2.5						
2014N214313_00	Elimination of 14C-GSK2118436 Following Oral Administration to Bile Duct-Intact and Bile Duct-Cannulated Mice (100 mg/kg)	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted](米国)	海外	社内資料	評価
RD2008/01676/00	Elimination of Radioactivity Following a Single Oral Administration of [14C]GSK2118436 to Male and Female Intact and Male Bile Duct-Cannulated CRL:CD(SD)TM Rats at a Target Dose Level of 10 mg/kg	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-RTP (米国)	海外	社内資料	評価
RD2009/00137/00	Elimination of Radioactivity Following a Single Oral (10 mg/kg) Administration of [14C]GSK2118436 to Male and Female Dogs	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted](米国)	海外	社内資料	評価
4.2.3.1						
CD2009/00799/00	GSK2118436B: Single-Dose Oral Toxicokinetic and Tolerability Study in Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	参考
CD2009/00563/00	GSK2118436B: Single-Dose and Twice Daily (BID) Escalation Oral Tolerability and Toxicokinetics Study in Dogs	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	参考

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.3.2						
2012N140412_00	GSK2118436B: 14-Day Oral Tolerability and Toxicokinetic Study in Crl:CD1(ICR) Mice	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-Ware (英国)	海外	社内資料	参考
2012N151126_00	GSK2118436B: A 26-Week Oral (Gavage) Toxicity Study in Mice with a 13-Week Interim Assessment	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (カナダ)	海外	社内資料	評価
CD2008/00951/02	GSK2118436A: 10-Day Oral Dose Range Toxicity Study in Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	参考
CD2008/01511/02	GSK2118436A: 4-Week Oral Toxicity Study in Rats Followed by a 2-Week Recovery Period	20[redacted]年[redacted]月～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
CD2010/00052/00	GSK2118436A: A 13 Week Oral Gavage Toxicity Study in the Rat Followed by a 4-week Recovery	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (カナダ)	海外	社内資料	評価
R2008/01229/00	GSK2118436B: 7-Day Oral Dose-Range Toxicity Study in Beagle Dogs	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-RTP (米国)	海外	社内資料	参考
CD2008/01503/02	GSK2118436A: 4-Week Oral Toxicity Study in Dogs Followed by a 2-Week Recovery Period	20[redacted]年[redacted]月～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
CD2010/00051/00	GSK2118436B: A 13 Week Twice Daily Oral Capsule Toxicity Study in the Beagle Dog Followed by a 4-Week Recovery	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (カナダ)	海外	社内資料	評価
4.2.3.3.1						
WD2008/01655/00	GSK2118436A: Bacterial Mutation Assay (Ames Test) with Salmonella typhimurium and Escherichia coli.	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-Ware (英国)	海外	社内資料	評価
2013N180401_00	GSK2118436B: Bacterial Mutation Assay (Ames Test) with Salmonella typhimurium and Escherichia coli	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (英国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	試験実施場所	報種類	掲載誌	評価／参考
4.2.3.3.1						
WD2008/01806/00	GSK2118436A: In Vitro Mutation Assay with L5178Y Mouse Lymphoma Cells at the TK Locus	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-Ware (英国)	海外	社内資料	評価
4.2.3.3.2						
WD2009/00233/00	GSK2118436A: Oral Bone Marrow Micronucleus Assay in Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-Ware (英国)	海外	社内資料	評価
4.2.3.5.1						
2010N107959_00	GSK2118436A: Oral Female Fertility, Early Embryonic and Embryo-Fetal Development Dose Range Study in Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	参考
2011N113146_01	GSK2118436A: Oral Female Fertility, Early Embryonic and Embryo-Fetal Development Study in Rats	20[redacted]年[redacted]月～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
4.2.3.7.3						
CD2009/00966/02	DNA Isolation and Papillomavirus Assessment of Skin Samples Obtained from a 4-Week Oral Toxicity Study in Dogs with BRAF Kinase Inhibitor GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	参考
4.2.3.7.7						
2012N132180_00	GSK2118436A: Effect on Body Temperature Following Repeat Daily Oral Administration in the Conscious CD1 Mouse	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	参考
2011N112335_00	GSK1120212B and GSK2118436B: 4-Week Twice Daily Oral Toxicity Study in Dogs	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2012N141617_00	GSK2118436B: Evaluation of phototoxicity in vitro on Balb/c 3T3 fibroblasts using the Neutral Red Uptake assay	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (英国)	海外	社内資料	評価
2014N193267_00	GSK2118436B: Single-Dose Oral Phototoxicity Evaluation in Hairless Mice	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted] (米国)	海外	社内資料	評価

第5部（臨床試験報告書）						
添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.1.1						
BRF113479	Determination of the Absolute Bioavailability of GSK2118436 Following a Single Oral Dose Co-Administered with an Intravenous Radiolabelled Microtracer of GSK2118436 in Subjects with BRAF Mutant Solid Tumors	2011年6月 ～2011年9月	GSK	海外	社内資料	参考
BRF113468	An Open Label Study to Examine the Effects of a High-Fat Meal and Particle Size on the Pharmacokinetics of Orally Administered GSK2118436 in Subjects with BRAF Mutation-Positive Tumor	2010年10月 ～2011年5月	GSK	海外	社内資料	参考
MEK115064	Determination of the Absolute Bioavailability of GSK1120212 Following a Single Oral Dose Co-Administered with an Intravenous Radiolabelled Microdose of GSK1120212 in Subjects with Solid Tumors	2011年6月 ～2011年12月	GSK	海外	社内資料	参考
MEK113709	An Open-Label, Two-Period, Randomized, Crossover Study to Evaluate the Effect of Food on the Single Dose Pharmacokinetics of the MEK Inhibitor, GSK1120212, in Subjects with Solid Tumors	2011年5月 ～2011年9月	GSK	海外	社内資料	参考
5.3.1.2						
MEK117134	A Phase IIa Study of the MEK Inhibitor GSK1120212 Monotherapy in the Treatment of Gemcitabine refractory Locally Advanced, Recurrent or Metastatic Biliary Tract Cancers	20[redacted] ～20[redacted] (データカットオフ)	グラクソ・スミスクライン	国内	社内資料	参考
5.3.1.4						
CD2009/00410/00	The Validation of a Method for the Determination of GSK2118436 and its Metabolite (GSK2285403) in Human Plasma (range 1 to 1000 ng/mL) using UHPLC-MS/MS	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
CD2010/00018/01	The Validation of a Method for the Determination of GSK2118436 and its Metabolites (GSK2285403 and GSK2167542) in Human Plasma (range 1 to 1000 ng/mL) using UHPLC-MS/MS	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
CD2010/00125/00	The Validation of a Method for the Determination of GSK2298683 in Human Plasma (range 5 to 5000 ng/mL) using UHPLC-MS/MS	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
2011N130965_01	The Validation of an UHPLC Method with Tandem Mass Spectrometric Detection to Quantify GSK2118436 and its Metabolites (GSK2285403 and GSK2167542) in Human Plasma	20[redacted] ～20[redacted]	[redacted] （イタリア）	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.1.4						
2011N130964_01	The Validation of an UHPLC Method with Tandem Mass Spectrometric Detection to Quantify GSK2298683 in Human Plasma (range 5 to 5000 ng/mL)	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（イタリア）	海外	社内資料	評価
2012N140703_00	Validation of a Method for the Determination of GSK2118436, GSK2285403, GSK2167542 and GSK1120212 in Human Plasma by HPLC with MS/MS Detection	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（米国）	海外	社内資料	評価
2012N139489_00	Validation of a Method for the Determination of GSK2298683 in Human Plasma by HPLC with MS/MS Detection	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（米国）	海外	社内資料	評価
2012N137093_00	Development and verification of analytical methods for HPLC fractionation followed by analysis by AMS of plasma samples from [redacted] Study Number 1/030	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（英国）	海外	社内資料	評価
2011N128435_00	Quantitation of Dexamethasone in Human Plasma via HPLC with MS/MS Detection	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（米国）	海外	社内資料	評価
FD2008/00210/00	The Validation of a Method for the Determination of Midazolam in Human Plasma (range 0.1 to 100 ng/mL) using HPLC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK Frythe（英国）	海外	社内資料	評価
2011N129508_00	Within-Study Analytical Performance Data for the Determination of GSK2118436 and its metabolites (GSK2285403 , GSK2167542 and GSK2298683) in Human Plasma GlaxoSmithKline Study Number BRF112680 A Phase I, Open-Label, Multiple-Dose, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of the BRAF Inhibitor GSK2118436 in Subjects with Solid Tumors	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK UM（米国）	海外	社内資料	評価
2011N128854_01	Interim Within-Study Analytical Performance Data for the Determination of GSK2285403 , GSK2167542 , GSK2298683 , GSK2118436 in Human Plasma for Support of BRF113710 GlaxoSmithKline Study Number BRF113710	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK UM（米国）	海外	社内資料	評価
2012N135609_00	Interim Within-Study Analytical Performance Data for the Determination of GSK2118436, GSK2285403 , GSK2167542, and GSK2298683 in Human Plasma for BRF113929 GlaxoSmithKline Study Number BRF113929– GSK2118436	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK UM（米国）	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.1.4						
2014N203744_00	Within-Study Analytical Performance Data for the Determination of GSK2118436 , GSK2285403 , GSK2167542 and GSK2298683 in Human Plasma GlaxoSmithKline Study Number BRF113683 GSK2118436 A Phase III randomized, open-label study comparing GSK2118436 to DTIC in previously untreated subjects with BRAF mutation positive advanced (Stage III) or metastatic (Stage IV) melanoma.	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
2012N137694_01	Quantification of GSK2118436 and its metabolites GSK2167542, GSK2285403 and GSK2298683 in Human Plasma Samples from Study BRF113771	20[redacted] ～20[redacted]	[redacted]（イタリア）	海外	社内資料	評価
2012N139451_00	Within-Study Analytical Performance Data for the Determination of GSK2118436, GSK2285403 , GSK2167542 ,and GSK2298683 in Human Plasma GlaxoSmithKline Study Number BRF113463 An Open-Label Study to Characterize the Absorption, Distribution, Metabolism and Elimination of a Single Oral 14C Labeled Dose of GSK2118436 in Subjects with BRAF mutant Solid Tumors	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
2012N139484_01	Within-Study Analytical Performance Data for the Determination of GSK2118436 and its Metabolites (GSK2285403, GSK2167542, and GSK2298683) in Human Plasma GlaxoSmithKline Study Number BRF113468 An Open Label Study to Examine the Effects of a High-Fat Meal and Particle Size on the Pharmacokinetics of Orally Administered GSK2118436 in Subjects with BRAF Mutation-Positive Tumors	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
2012N131919_00	Within-Study Analytical Performance Data for the Determination of GSK2118436 in Human Plasma GlaxoSmithKline Study Number BRF113479	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
2012N137095_00	Analysis of plasma samples derived from humans administered a single intravenous dose of 50 µg, 200 nCi GSK2118436, for 14C-content and [14C]GSK2118436 concentrations, by Accelerator Mass Spectrometry and HPLC	20[redacted] ～20[redacted]	[redacted]（英国）	海外	社内資料	評価
2011N130418_00	Quantitation of Dexamethasone in Human Plasma via HPLC with MS/MS Detection	20[redacted] ～20[redacted]	[redacted]（米国）	海外	社内資料	評価
2010N104053_00	Within-Study Analytical Performance Data for the Determination of Midazolam in Human Plasma GlaxoSmithKline Study Number BRF112680	20[redacted] ～20[redacted]	GSK Ware （英国）	海外	社内資料	評価

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5.3.1.4						
2012N144675_00	Interim Within-Study Analytical Performance Data for the Determination of GSK2118436, GSK2285403, GSK2167542, and GSK2298683 in Human Plasma GlaxoSmithKline Study Number BRF113220 An Open-Label, Dose-Escalation, Phase I Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of the BRAF Inhibitor GSK2118436 in Combination with the MEK Inhibitor GSK1120212 in Subjects with BRAF Mutant Metastatic Melanoma	20[redacted] ～20[redacted]	[redacted] （イタリア）	海外	社内資料	評価
2012N145030_00	Interim Within-Study Analytical Performance Data for the Determination of GSK1120212 in Human Plasma GlaxoSmithKline Study Number BRF113220 An Open-Label, Dose-Escalation, Phase I Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of the BRAF Inhibitor GSK2118436 in Combination with the MEK Inhibitor GSK1120212 in Subjects with BRAF Mutant Metastatic Melanoma	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
CD2008/00957/00	Validation of a Method for the Determination of GSK1120212 in Human Plasma (range 0.25 to 250 ng/mL) Using HPLC-MS/MS	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
2010N108094_00	Supplemental Validation Data to "The Validation of a Method for the Determination of GSK1120212 in Human Plasma (range 0.25 to 250 ng/mL) Using HPLC-MS/MS"	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価
2011N125717_00	Validation of a Method for the Determination of GSK1120212 in Human Plasma by HPLC with MS/MS Detection	20[redacted] ～20[redacted]	[redacted] （米国）	海外	社内資料	評価
2013N168357_00	Validation of a Method for the Determination of GSK1120212 in Human Plasma by HPLC with MS/MS Detection	20[redacted] ～20[redacted]	[redacted] （米国）	海外	社内資料	評価
PBC097-052	Validation of an Analytical Method for Determination of GSK1120212 in Human Plasma by LC-MS/MS	20[redacted] ～20[redacted]	[redacted] （日本）	国内	社内資料	評価
2011N126160_00	The Validation of a Method for the Determination of [14C]-GSK1120212 in human plasma (range 1.1 to 104 pg/mL) using AMS	20[redacted] ～20[redacted]	GSK Ware（英国）	海外	社内資料	評価
CD2008/00913/00	The Validation of a Method for the Determination of Gemcitabine and 2,2-Difluoro-2-Deoxyuridine in Human Plasma (ranges 20 to 5000 ng/mL and 100 to 25000 ng/mL, respectively) using LC-MS/MS	20[redacted] ～20[redacted]	GSK UM（米国）	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.1.4						
PBC097-053	Validation of an Analytical Method for Determination of Gemcitabine and dFdU in Human Plasma by LC-MS/MS	20[redacted]年[redacted]月～20[redacted]年[redacted]月	[redacted]（日本）	国内	社内資料	評価
2011N121812 00	Within-Study Analytical Performance Data for the Determination of GSK1120212 in Human Plasma GlaxoSmithKline Study Number MEK111054 An Open-Label, Multiple-Dose, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of the MEK Inhibitor GSK1120212 in Subjects with Solid Tumors or Lymphoma	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK UM（米国）	海外	社内資料	評価
2011N121174_00	Within-Study Analytical Performance Data for the Determination of GSK1120212 in Human Plasma GlaxoSmithKline Study Number MEK113583 An open-Label, Multi-Center Study to Investigate the Objective Response Rate, Safety, and Pharmacokinetics of GSK1120212, a MEK inhibitor, in BRAF Mutation-positive Melanoma subjects previously Treated with a BRAF inhibitor.	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK UM（米国）	海外	社内資料	評価
2011N128879_00	Within-Study Analytical Performance Data for the Determination of GSKl120212 in Human Plasma GlaxoSmithKline Study Number MEKl12111 - GSKl120212 A Phase IE Combination Study ofMEK inhibitor GSKl120212 with Gemcitabine in Subjects with Solid Tumors	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK UM（米国）	海外	社内資料	評価
2012N142529_01	Within-Study Analytical Performance Data for the Determination of dFdU and Gemcitabine in Human Plasma (Gemcitabine Only) GlaxoSmithKline Study Number MEK112111 - GEMCITABINE A Phase IB Combination Study of MEK inhibitor GSK1120212 with Gemcitabine in Subjects with Solid Tumors	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK UM（米国）	海外	社内資料	評価
2011N128882_00	Within-Study Analytical Performance Data for the Determination of GSKl120212 in Human Plasma GlaxoSmithKline Study Number MEKl13708 An Open-Label Mass Balance Study to Investigate the Absorption, Distribution, Metabolism and Elimination of a Single Oral Dose of MEK Inhibitor [14C]GSKl120212 in Male Subjects with Solid Tumors	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK UM（米国）	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.1.4						
2012N136471_00	Within-Study Analytical Performance Data for the Determination of GSKl120212 in Human Plasma GlaxoSmithKline Study Number MEKI13709 An Open-label, Two-Period, Randomized, Crossover Study to Evaluate the Effect of Food on the Pharmacokinetics of the MEK inhibitor, GSKl120212, in Subjects with Solid Tumors.	[redacted]	GSK UM（米国）	海外	社内資料	評価
2012N136458_00	Within-Study Analytical Performance Data for the Determination of GSKl120212 in Human Plasma GlaxoSmithKline Study Number MEKl15064 Determination of the Absolute Bioavailability of GSKl120212 Following a Single Oral Dose Co-Administered with an Intravenous Radiolabelled Microdose of GSKl120212 in Healthy Subjects.	[redacted]	GSK UM（米国）	海外	社内資料	評価
2012N134151_00	Within-Study Analytical Perfonnance Data for the Determination of [14C]-GSKI120212 in Human Plasma. GlaxoSmithKline Study Number MEK115064 Detennination of the Absolute Bioavailability of GSK1120212 Following a Single Oral Dose Co-Administered with a 5 µg 200nCi Intravenous Radiolabelled Microdose of [14C]-GSKI120212.	[redacted]	GSK Ware（英国）	海外	社内資料	評価
2012N135243_00	Interim Within-Study Analytical Performance Data for the Determination of GSK1120212 in Human Plasma GlaxoSmithKline Study Number MEK114267 A Phase III randomized, open-label study comparing GSK1120212 to chemotherapy in subjects with advanced or metastatic BRAF V600EIKID mutation-positive melanoma	[redacted]	GSK UM（米国）	海外	社内資料	評価
2013N163232_00	Measurement of Plasma GSK1120212 and Gemcitabine Concentrations in "A Phase I Trial of GSK1120212 and GSK1120212 in Combination with Gemcitabine in Japanese Subjects with Solid Tumors"	[redacted]	[redacted]（日本）	国内	社内資料	評価
5.3.2.1						
2011N129517_00	An Investigation of the in vitro Protein Binding of GSK2118436 and Its Circulating Metabolites GSK2298683 (M4), GSK2285403 (M7) and GSK2167542 (M8) in Male Human Plasma	[redacted]	GSK-UM (米国)	海外	社内資料	評価
5.3.2.2						
UD2010/00042/00	Assessment of possible P-glycoprotein (Pgp)-mediated efflux and intrinsic permeability of GSK2285403A, GSK2167542A and GSK2298683B, 3 known metabolites of GSK2118436, across MDR1-MDCKII cell monolayers	[redacted]	[redacted]（米国）	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.2.2						
2014N204589_00	An in vitro investigation into the uptake of GSK2118436, GSK2285403, GSK2167542, and GSK2298683 in cryopreserved human hepatocytes and into cells singly overexpressing OATP1B1, OATP1B3 or OATP1A2.	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2014N218314_00	An in vitro investigation into the uptake of GSK2118436, GSK2285403 and GSK2167542 into cells singly overexpressing OATP1A2.	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00143/01	An In Vitro Investigation of the Inhibition by GSK2118436B of Xenobiotic Transport Via Human P-Glycoprotein, Heterologously Expressed in MDCKII Cells.	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
2011N119324_01	An In Vitro Investigation of the Inhibition of Xenobiotic Transport Via Human P-Glycoprotein, Heterologously Expressed in MDCKII Cells by the Metabolites of GSK2118436: GSK2285403, GSK2298683 and GSK2167542.	20[redacted]年[redacted]月 ～20[redacted]年8月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
2011N112849_00	An In Vitro Investigation into the Inhibition by GSK2118436 of Xenobiotic Transport via Human Breast Cancer Resistance Protein Heterologously Expressed in MDCKII Cells.	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2011N119323_00	An In Vitro Investigation into the Inhibition of Xenobiotic Transport via Human Breast Cancer Resistance Protein Heterologously Expressed in MDCKII Cells by the Metabolites of GSK2118436: GSK2285403, GSK2298683 & GSK2167542	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00116/00	An In Vitro Investigation into the Inhibition by GSK2118436 of Xenobiotic Transport via Human OATP1B1 and OATP1B3	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N110987_00	An In Vitro Investigation into the Inhibition by GSK2298683 of Xenobiotic Transport via Human OATP1B1 and OATP1B3	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N110986_00	An In Vitro Investigation into the Inhibition by GSK2285403 of Xenobiotic Transport via Human OATP1B1 and OATP1B3	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2010/00386/00	An In Vitro Investigation into the Inhibition by GSK2167542 of Xenobiotic Transport via Human OATP1B1 and OATP1B3	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.2.2						
2012N131808_01	An In Vitro Investigation into the Inhibition by GSK2118436 and its circulating metabolites, GSK2298683, GSK2285403 and GSK2167542 of Xenobiotic Transport via Human OAT1 and OAT3.	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-Ware (英国)	海外	社内資料	評価
2014N220059_00	In vitro evaluation of GSK2118436, GSK2285403, GSK2167542 and GSK2298683 as inhibitors of OCT2 transporter	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	[redacted] (日本)	国内	社内資料	評価
CD2009/00471/00	An In Vitro Investigation of the Hepatic Metabolism of [14C]GSK2118436 in the Mouse, Rat, Female Rabbit, Dog, Cynomolgus Monkey and Human	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00061/00	An In Vitro Investigation of the Potential for GSK2118436 Bioactivation Following Incubation of [14C]GSK2118436 with Human Liver Microsomes	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2009/00079/00	An In Vitro Investigation into the Human Oxidative Enzymology of GSK2118436	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2010/00233/01	An In Vitro Investigation into the Human Oxidative Enzymology of [14C]GSK2118436	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
2011N129873_00	A preliminary in vitro investigation into the human oxidative enzymology of GSK2167542, GSK2285403 and GSK2298683, the metabolites of GSK2118436	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
CD2008/01428/00	An In Vitro Evaluation of the Effect of GSK2118436 on mRNA levels of Cytochrome P450 genes in Cultured Human Hepatocytes	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N110340_00	An In Vitro Investigation into the Inhibition of Human Cytochrome P450 Enzymes: CYP1A2, CYP2C9, CYP2C19 and CYP2D6 by GSK2118436	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
UH2008/00115/03	Preliminary Drug Metabolism and Pharmacokinetics of GSK2118436	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月 (20[redacted]年[redacted]月改訂)	GSK-Collegeville (米国) [redacted] (英国)	海外	社内資料	参考
CD2009/00012/00	An In Vitro Investigation into the Inhibition of Human Cytochrome P450 Enzymes by GSK2118436	20[redacted]年[redacted]月 ～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.2.2						
2010N110991_00	An In vitro Investigation into the inhibition of Human Cytochrome P450 Enzymes by GSK2298683	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N111279_00	An In vitro Investigation into the inhibition of Human Cytochrome P450 Enzymes by GSK2285403	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK-UM (米国)	海外	社内資料	評価
2010N111291_01	An In vitro Investigation into the inhibition of Human Cytochrome P450 Enzymes by GSK2167542	20[redacted]年[redacted]月～20[redacted]年[redacted]月(20[redacted]年[redacted]月改訂)	GSK-UM (米国)	海外	社内資料	評価
5.3.3.2						
2011N112237_00	A Preliminary Investigation of the Metabolites of GSK2118436 in Human Plasma and Urine, Following Oral Administration to Cancer Patients	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK	海外	社内資料	参考
2011N114097_00	An Open-Label Study to Characterize the Absorption, Distribution, Metabolism and Elimination of a Single Oral ^{14}C Labeled Dose of GSK2118436 in Subjects with BRAF mutant Solid Tumors	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK	海外	社内資料	参考
2011N128751_00	A Metabolism Study of GSK2118436 Following a Single Oral Suspension Administration (95 mg; 80μCi) of [^{14}C]GSK2118436 to Subjects with BRAF Mutant Solid Tumors	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK	海外	社内資料	参考
2012N134931_00	Preliminary Characterization of Metabolites in Human Plasma and Urine Following Repeat Oral Administration of GSK1120212 in Patients	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK	海外	社内資料	参考
2011N124060_00	An Open-Label Mass Balance Study to Investigate the Absorption, Distribution, Metabolism, and Elimination of a Single Oral Dose of MEK Inhibitor [^{14}C]GSK1120212 in Male Subjects with Solid Tumors	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK	海外	社内資料	参考
2012N136011_00	A Metabolism Study of GSK1120212 Following a Single Oral Solution Administration (2 mg) of [^{14}C]GSK1120212 to Male Subjects with Solid Tumors	20[redacted]年[redacted]月～20[redacted]年[redacted]月	GSK	海外	社内資料	参考

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.3.4						
BRF113771	A Four-Part, Open-Label Study to Evaluate the Effects of Repeat Dose GSK2118436 on the Single Dose Pharmacokinetics of Warfarin, the Effects of Repeat Dose Oral Ketoconazole and Oral Gemfibrozil on the Repeat Dose Pharmacokinetics of GSK2118436, and the Repeat Dose Pharmacokinetics of GSK2118436 in Subjects with BRAF Mutant Solid Tumors	2011年7月 ～2012年11月	GSK	海外	社内資料	参考
MEK112111	A Phase 1B combination study of MEK inhibitor GSK1120212 with gemcitabine in subjects with solid tumors	2009年8月 ～2011年7月	GSK	海外	社内資料	参考
5.3.3.5						
2011N113667_00	Population Pharmacokinetics of GSK2118436 in Subjects with Solid Tumors	20[redacted]年[redacted]月報告	GSK	海外	社内資料	参考
2011N130818_00	Covariate Analysis of Dabrafenib Metabolites Concentrations (Hydroxy-Dabrafenib, Carboxy-Dabrafenib and Desmethyl-Dabrafenib)	20[redacted]年[redacted]月報告	GSK	海外	社内資料	参考
2011N120468_00	Exposure-Response Analysis of the Effects of Dabrafenib in Subjects with BRAF mutation positive melanoma	20[redacted]年[redacted]月報告	GSK	海外	社内資料	参考
2011N120486_00	POPULATION PHARMACOKINETICS OF TRAMETINIB IN SUBJECTS WITH CANCER (PROTOCOLS MEK111054, MEK113583, AND MEK114267)	20[redacted]年[redacted]月報告	GSK	海外	社内資料	参考
2011N130902_00	Exposure-Response Analysis of the Effects of Trametinib, a MEK inhibitor, on Efficacy and Safety Endpoints	20[redacted]年[redacted]月報告	GSK	海外	社内資料	参考

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.3.5						
2012N144949_02	Population Pharmacokinetics and Exposure-Response Analysis of Dabrafenib and Trametinib in Combination	20[redacted]月報告	GSK	海外	社内資料	参考
2013N184875_00	Population Pharmacokinetics and Exposure-Response Analysis of Dabrafenib and Trametinib in Combination for Study MEK115306	20[redacted]月報告	GSK	海外	社内資料	参考
5.3.4.2						
BRF116056	Exposure-Response Analysis of the Effect of GSK2118436 and its Metabolites on ECG Parameters in Study BRF116056	2015年3月報告	GSK	海外	社内資料	参考
MEK114784	Exposure-Response Analysis of the Effect of GSK1120212 on ECG Parameters in Study MEK114784	2015年3月報告	GSK	海外	社内資料	参考
5.3.5.1						
BRF113683	A Phase III randomized, open-label study comparing GSK2118436 to DTIC in previously untreated subjects with BRAF mutation positive advanced (Stage III) or metastatic (Stage IV) melanoma	2011年2月2日～2011年12月19日(データカットオフ)	GSK	海外	社内資料	評価
MEK114267	MEK114267, a Phase III randomized, open-label study comparing GSK1120212 to chemotherapy in subjects with advanced or metastatic BRAF V600E/K mutation-positive melanoma	2010年11月23日～2011年10月26日(データカットオフ)	GSK	海外	社内資料	評価
MEK116513	A Phase III, randomised, open-label study comparing the combination of the BRAF inhibitor dabrafenib and the MEK inhibitor trametinib to the BRAF inhibitor vemurafenib in subjects with unresectable (stage IIIc) or metastatic (stage IV) BRAF V600E/K mutation positive cutaneous melanoma	2012年6月4日～2014年4月17日(データカットオフ)	GSK	海外	社内資料	評価
MEK115306	A Phase III, randomized, double-blinded study comparing the combination of the BRAF inhibitor, dabrafenib and the MEK inhibitor, trametinib to dabrafenib and placebo as first-line therapy in subjects with unresectable (Stage IIIC) or metastatic (Stage IV) BRAF V600E/K mutation-positive cutaneous melanoma.	2012年5月4日～2013年8月26日(データカットオフ)	GSK	海外	社内資料	評価
MEK115306	A Phase III, randomized, double-blinded study comparing the combination of the BRAF inhibitor, dabrafenib and the MEK inhibitor, trametinib to dabrafenib and placebo as first-line therapy in subjects with unresectable (Stage IIIC) or metastatic (Stage IV) BRAF V600E/K mutation-positive cutaneous melanoma.（第2回データカットオフ）	2012年5月4日～2015年1月12日(第2回データカットオフ)	GSK	海外	社内資料	評価

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.5.1						
BRF113220 Part C	An Open-Label, Dose-Escalation, Phase IB/II Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of the BRAF Inhibitor GSK2118436 in Combination with the MEK Inhibitor GSK1120212 in Subjects with BRAF Mutant Metastatic Melanoma (Part C)（第1回データカットオフ）	2010年12月14日～2012年5月31日(データカットオフ)	GSK	海外	社内資料	評価
BRF113220 Part C	An Open-Label, Dose-Escalation, Phase IB/II Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of the BRAF Inhibitor GSK2118436 in Combination with the MEK Inhibitor GSK1120212 in Subjects with BRAF Mutant Metastatic Melanoma (Part C)（第2回データカットオフ）	2010年12月14日～2[redacted](データカットオフ)	GSK	海外	社内資料	評価
5.3.5.2						
BRF116056	BRAF遺伝子変異陽性の日本人固形癌患者を対象としたGSK2118436の安全性、忍容性及び薬物動態を検討する非盲検用量漸増第Ｉ相試験	2012年5月11日～2014年8月1日(データカットオフ)	グラクソ・スミスクライン	国内	社内資料	評価
BRF113929	A Phase II Open-Label, Two-Cohort, Multicentre Study of GSK2118436 as a Single Agent in Treatment Naïve and Previously Treated Subjects with BRAF Mutation-Positive Metastatic Melanoma to the Brain (BREAK-MB)（第1回データカットオフ）	2011年2月1日～2011年11月28日(データカットオフ)	GSK	海外	社内資料	参考
BRF113929	A Phase II Open-Label, Two-Cohort, Multicentre Study of GSK2118436 as a Single Agent in Treatment Naïve and Previously Treated Subjects with BRAF Mutation-Positive Metastatic Melanoma to the Brain (BREAK-MB)（試験終了）	2011年2月1日～2013年4月8日	GSK	海外	社内資料	参考
BRF113710	A Phase II single-arm, open-label study of GSK2118436 in BRAF-mutant metastatic melanoma	2010年8月9日～2011年7月7日(データカットオフ)	GSK	海外	社内資料	参考
BRF112680	A Phase I, Open-Label, Multiple-Dose, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of the BRAF Inhibitor GSK2118436 in Subjects with Solid Tumors（第1回データカットオフ）	2009年5月27日～2011年3月25日(データカットオフ)	GSK	海外	社内資料	参考
BRF112680	A Phase I, Open-Label, Multiple-Dose, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of the BRAF Inhibitor GSK2118436 in Subjects with Solid Tumors（試験終了）	2009年5月27日～2012年3月19日	GSK	海外	社内資料	参考

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.5.2						
MEK114784	日本人固形癌患者を対象としたGSK1120212単剤及びGSK1120212とゲムシタビン併用第I相臨床試験	2011年1月24日～2013年7月8日	グラクソ・スミスクライン	国内	社内資料	評価
MEK113583	An Open-Label, Multi-Center Study to Investigate the Objective Response Rate, Safety, and Pharmacokinetics of GSK1120212, a MEK inhibitor, in BRAF Mutation-Positive Melanoma Subjects Previously Treated either with or without a BRAF Inhibitor（第1回データカットオフ）	2009年11月27日～2011年7月25日（データカットオフ）	GSK	海外	社内資料	参考
MEK113583	An Open-Label, Multi-Center Study to Investigate the Objective Response Rate, Safety, and Pharmacokinetics of GSK1120212, a MEK inhibitor, in BRAF Mutation-Positive Melanoma Subjects Previously Treated either with or without a BRAF Inhibitor（試験終了）	2009年11月27日～2013年1月17日	GSK	海外	社内資料	参考
MEK111054	An Open-Label, Multiple-Dose, Dose-Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of the MEK Inhibitor GSK1120212 in Subjects with Solid Tumors or Lymphoma	2008年7月31日～2011年6月7日（データカットオフ）	GSK	海外	社内資料	参考
MEK116885	BRAF V600E 又はV600K 変異陽性の進行固形癌（第I 相部分）及び皮膚悪性黒色腫（第II 相部分）を有する患者を対象にGSK2118436とGSK1120212 の併用療法の安全性、忍容性、薬物動態及び有効性を検討する日本での非盲検第I/II 相試験	2013年8月15日～2014年9月18日（データカットオフ）	グラクソ・スミスクライン	国内	社内資料	評価
BRF113220 Part ABD	An Open-Label, Dose-Escalation, Phase IB/II Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of the BRAF Inhibitor GSK2118436 in Combination with the MEK Inhibitor GSK1120212 in Subjects with BRAF Mutant Metastatic Melanoma (Parts ABD)	Part A、B：2010年3月19日～2012年5月25日（データカットオフ） Part D：2010年3月19日～2012年9月25日（データカットオフ）	GSK	海外	社内資料	参考
5.3.5.3						
2011N112391_00	Integrated Summary of Safety (dabrafenib)	－	GSK	海外	社内資料	参考

添付資料番号	タイトル	試験実施期間	治験依頼者	報種類	掲載誌	評価／参考
5.3.5.3						
2012N136426_00	Integrated Summary of Safety (trametinib)	－	GSK	海外	社内資料	参考
5.3.6						
－	Dabrafenib Periodic Benefit Risk Evaluation Report 27 February 2014 to 26 August 2014	－	GSK	海外	社内資料	参考
－	Trametinib Periodic Benefit Risk Evaluation Report 29 May 2013 to 28 August 2014	－	GSK	海外	社内資料	参考

1.12.2. 提出すべき資料がない項目一覧

第4部のうち、以下の項目

4.2.1.4	薬力学的薬物相互作用試験
4.2.2.6	薬物動態学的薬物相互作用
4.2.2.7	その他の薬物動態試験
4.2.3.4	がん原性試験
4.2.3.5.2	胚･胎児発生に関する試験
4.2.3.5.3	出生前及び出生後の発生並びに母体の機能に関する試験
4.2.3.5.4	新生児を用いた試験
4.2.3.6	局所刺激性試験
4.7.3.7.1	抗原性試験
4.2.3.7.2	免疫毒性試験
4.2.3.7.4	依存性試験
4.2.3.7.5	代謝物の毒性試験
4.2.3.7.6	不純物の毒性試験
4.3	参考文献

第5部のうち、以下の項目

5.3.1.3	In Vitro-In Vivoの関連を検討した試験報告書
5.3.2.3	他のヒト生体試料を用いた試験報告書
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
5.3.3.3	内因性要因を検討したPK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
5.3.5.4	その他の試験報告書