7.5 Tabulated Index of Mechanistic and Systems Toxicology (SYSTOX) Studies

Study Type: Non-clinical studies

Full reference	Citation & File name	Filepath
Carine Poussin, Alexandra Laurent, Manuel C. Peitsch, Julia Hoeng, Hector De Leon. Systems toxicology-based assessment of the candidate modified risk tobacco product THS2.2 for the adhesion of monocytic cells to human coronary arterial endothelial cells. Toxicology 339: 73–86, 2016	1604_CVD_Adhesion_Assay_Pub	7 STUDYANA\75 SYSTOX\InVitro\CVD Assays\1604_CVD_Adhesion_Assay_Pub
Philip Morris International. Unpublished on file data. Internal Report. Study plan translational organotypic acute human bronchial tissues study (ths2.2) (s 170900), 2013	1709_Organotypic_Bronch_SP	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1709_Organotypic_Bronch_SP
Philip Morris International. Unpublished on file data. Internal Report. In vitro assessment of the acute exposure of organotypic human bronchial tissue cultures to aerosol produced by the tobacco heating system 2.2 (study number s1709), 2016	1709_Organotypic_Bronch_SR	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1709_Organotypic_Bronch_SR
Anita R. Iskandar, Carole Mathis, Walter K. Schlage, Stefan Frentzel, Patrice Leroy, Yang Xiang, Alain Sewer, Shoaib Majeed, Laura Ortega-Torres, Stephanie Johne, Emmanuel Guedj, Keyur Trivedi, Gilles Kratzer, Celine Merg, Ashraf Elamin, Florian Martin, Nikolai V. Ivanov, Manuel C. Peitsch, Julia Hoeng. A systems toxicology approach for comparative assessment: Biological impact of an aerosol from a candidate modified-risk tobacco product and cigarette smoke on human organotypic bronchial epithelial cultures. Submitted to the journal Toxicology In Vitro, 2016	1709_Organotypic_Bronch_Pub	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1709_Organotypic_Bronch_Pub

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Full reference	Citation & File name	Filepath
Philip Morris International. Unpublished on file data. Internal Report. Study plan translational organotypic acute human nasal tissues study (ths2.2)- (s 172200), 2013	1722_Organotypic_Nasal_SP	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1722_Organotypic_Nasal_SP
Philip Morris International. Unpublished on file data. Internal Report. In vitro assessment of acute exposure of ths2.2 aerosol on organotypic acute human nasal cultures (study plan number 172200), 2016	1722_Organotypic_Nasal_SR	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1722_Organotypic_Nasal_SR
Anita R. Iskandar, Carole Mathis, Florian Martin, Patrice Leroy, Alain Sewer, Shoaib Majeed, Diana Kuehn, Keyur Trivedi, Davide Grandolfo, Maciej Cabanski, Emmanuel Guedj, Celine Merg, Stefan Frentzel, Nikolai V. Ivanov, Manuel C. Peitsch and Julia Hoeng. 3-D Nasal Cultures: Systems Toxicological Assessment of a Candidate Modified-Risk Tobacco Product, Epub July 7, 2016; http: //dx.doi.org/10.14573/altex.1605041	1722_Organotypic_Nasal_Pub	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1722_Organotypic_Nasal_Pub
Philip Morris International. Unpublished on file data. Internal Report. Study plan translational organotypic acute human buccal tissues study (ths2.2) (s174300), 2014	1743_Organotypic_Buccal_SP	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1743_Organotypic_Buccal_SP
Philip Morris International. Unpublished on file data. Internal Report. Assessment of the effects of acute exposure of ths2.2 aerosol on organotypic human buccal cultures (study number 174300), 2016	1743_Organotypic_Buccal_SR	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1743_Organotypic_Buccal_SR

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Full reference	Citation & File name	Filepath
Filippo Zanetti, Alain Sewer, Carole Mathis, Anita R. Iskandar, Radina Kostadinova, Walter K. Schlage, Patrice Leroy, Shoaib Majeed, Emmanuel Guedj, Keyur Trivedi, Florian Martin, Ashraf Elamin, Céline Merg, Nikolai V. Ivanov, Stefan Frentzel, Manuel C. Peitsch, and Julia Hoeng. Systems Toxicology Assessment of the Biological Impact of a Candidate Modified Risk Tobacco Product on Human Organotypic Oral Epithelial Cultures. Chem. Res. Toxicol. 29, pp 1252−1269, 2016	1743_Organotypic_Buccal_Pub	7 STUDYANA\75 SYSTOX\InVitro\OrganInvest\1743_Organotypic_Buccal_Pub
Ignacio Gonzalez-Suarez, Florian Martin, Diego Marescotti, Emmanuel Guedj, Stefano Acali, Stephanie Johne, Remi Dulize, Karine Baumer, Dariusz Peric, Didier Goedertier, Stefan Frentzel, Nikolai V. Ivanov, Carole Mathis, Julia Hoeng, and Manuel C. Peitsch. In Vitro Systems Toxicology Assessment of a Candidate Modified Risk Tobacco Product Shows Reduced Toxicity Compared to That of a Conventional Cigarette. Chem. Res. Toxicol., 29 (1), pp 3–18, 2016	167321_High_Content_Screening_SysTOX21_Pub	7 STUDYANA\75 SYSTOX\InVitro\CVD Assays\167321_High_Content_Screening_TOX21_Pub
Marco van der Toorn, Stefan Frentzel, Hector De Leon, Didier Goedertier, Manuel C. Peitsch, Julia Hoeng. Aerosol from a candidate modified risk tobacco product has reduced effects on chemotaxis and transendothelial migration compared to combustion of conventional cigarettes. Food and Chemical Toxicology 86: 81-87, 2015	1739_CVD_Migration_Assay_Pub	7 STUDYANA\75 SYSTOX\InVitro\CVD Assays\1739_CVD_Migration_Assay_Pub

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Full reference	Citation & File name	Filepath
Arkadiusz K. Kuczaj, Markus Nordlund, Santhosh Jarayaju, Ed Komen, Tobias Krebs, Manuel Peitsch, Julia Hoeng. Aerosol flow in the Vitrocell R 24/48 exposure system: flow mixing and aerosol coalescence. Applied In Vitro Toxicology. September 2(3): pp 165-174, 2016 doi:10.1089/aivt.2016.0009.	Flow_Sim_Vitrocell_Pub	7 STUDYANA\75 SYSTOX\InVitro\Vitrocell\ Flow_Sim_Vitrocell_Pub
Philip Morris International. Unpublished on file data. Internal Report. Study plan in vivo evaluation of the effects of Zurich mrtp (del/c3/fr1/rdo) on the respiratory and cardiovascular systems of apo lipoprotein e-deficient mice (study number 15015), 2013	15015_CVD_Resp_ApoE _SW_SP	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\15015_CVD_Resp_ApoE _SW_SP
Philip Morris International. Unpublished on file data. Internal Report. Study report part 1. In vivo evaluation of the effects of ths2.2 mrtp (del/c3/fr1/rdo) on the respiratory and cardiovascular systems of apolipoprotein e-deficient mice (study number 15015), 2014	15015_CVD_Resp_ApoE _SW_SR_Part1	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\15015_CVD_Resp_ApoE _SW_SR_Part 1
Philip Morris International. Unpublished on file data. Internal Report. Study Report. In vivo evaluation of the effects of THS2.2 on the respiratory and cardiovascular systems of Apolipoprotein e-deficient mice Part 2: Metabolic endpoints-Insulin resistance (Study number 15015), 2014	15015_CVD_Resp_ApoE _SW_SR_Part2	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\15015_CVD_Resp_ApoE _SW_SR_Part 2

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Full reference	Citation & File name	Filepath
Philip Morris International. Unpublished on file data. Internal Report. Study 150155 report Systems toxicology data from samples harvested in the study 15015: apoe−/− zrh switching study to characterize the toxicity of ths2.2 in apoe−/− mice, 2014	15015_CVD_Resp_ApoE_SW_SR_Part3	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\ 15015_CVD_Resp_ApoE_SW_SR_Part 3
Philip Morris International. Unpublished on file data. Internal Report. Zora Biosciences Oy. Lipidomic characterization of ApoE(-/-) mouse tissue and plasma samples after smoke exposure, 2014	15015_CVD_Resp_ApoE_SW_SR_Part4	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\ 15015_CVD_Resp_ApoE_SW_SR_Part 4
Philip Morris International. Unpublished on file data. Internal Report. Histovia. Histopathological and Morphometrical Assessment of Lung, Nose, and Liver of ApoE-Deficient Mice. Report, 2014	15015_CVD_Resp_ApoE_SW_SR_Part5	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\ 15015_CVD_Resp_ApoE_SW_SR_Part 5
Philip Morris International. Unpublished on file data. Internal Report. Study report In vivo evaluation of the effects of THS2.2 mrtp (del/c3/fr1/rdo) on the respiratory and cardiovascular systems of apolipoprotein e-deficient mice (study number 15015) part 6: Consolidated results and statistical tables from delegated phase 5, 2014	15015_CVD_Resp_ApoE_SW_SR_Part6	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\ 15015_CVD_Resp_ApoE_SW_SR_Part 6

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Full reference	Citation & File name	Filepath
Philip Morris International. Unpublished on file data. Internal Report. Test report from ABF. Determination of HPMA, total NNAL, SPMA, CEMA, 8-OHdG, MDA, 4-HNE and 9 eicosanoids in mice urine samples and of Nic/Cot in mice plasma samples of PMI Study 15015, 2014	15015_CVD_Resp_ApoE_SW_SR_Part7	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\ 15015_CVD_Resp_ApoE_SW_SR_Part 7
Philip Morris International. Unpublished on file data. Internal Report. Numira: Phase report. MicroCt Analyses of ApoE-/- Mouse aortas, 2014	15015_CVD_Resp_ApoE_SW_SR_Part8	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\ 15015_CVD_Resp_ApoE_SW_SR_Part 8
Philip Morris International. Unpublished on file data. Internal Report. Analysis report determination of oxysterols and cholesterol in plasma from a study investigating the effects of zurich mrtp (del/c3/fr1/rdo) on the respiratory and cardiovascular systems of apo lipoprotein e-deficient mice using lc-hr-ms and lc-cad study number 150156, 2014	15015_CVD_Resp_ApoE_SW_SR_Part9	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\ 15015_CVD_Resp_ApoE_SW_SR_Part 9
Philip Morris International. Unpublished on file data. Internal Report. Phase Report In vivo evaluation of the effects of THS2.2 on the respiratory and cardiovascular systems of Apolipoprotein e-deficient mice Histopathology of Pancreas and kidney (study number 15015), 2014	15015_CVD_Resp_ApoE_SW_SR_Part10	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\ 15015_CVD_Resp_ApoE_SW_SR_Part 10

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Full reference	Citation & File name	Filepath
Blaine Phillips, Emilija Veljkovic, Stephanie Boue, Walter K. Schlage, Gregory Vuillaume, Florian Martin, Bjoern Titz, Patrice Leroy, Ansgar Buettner, Ashraf Elamin, Alberto Oviedo, Maciej Cabanski, Hector De Leon, Emmanuel Guedj, Thomas Schneider, Marja Talikka, Nikolai V. Ivanov, Patrick Vanscheeuwijck, Manuel C. Peitsch, and Julia Hoeng. An 8-Month Systems Toxicology Inhalation/Cessation Study in Apoe-/- Mice to Investigate Cardiovascular and Respiratory Exposure Effects of a Candidate Modified Risk Tobacco Product, THS 2.2, Compared With Conventional Cigarettes. TOXICOLOGICAL SCIENCES, 149(2): 411–432, 2016	15015_CVD_Resp_ApoE_SW_Pub_Main	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\15015_CVD_Resp_ApoE_SW_Pub_Main
Bjoern Titz, Stephanie Boue, Blaine Phillips, Marja Talikka, Terhi Vihervaara, Thomas Schneider, Catherine Nury, Ashraf Elamin, Emmanuel Guedj, Michael J. Peck, Walter K. Schlage, Maciej Cabanski, Patrice Leroy, Gregory Vuillaume, Florian Martin, Nikolai V. Ivanov, Emilija Veljkovic, Kim Ekroos, Reijo Laaksonen, Patrick Vanscheeuwijck, Manuel C. Peitsch, and Julia Hoeng. Effects of Cigarette Smoke, Cessation, and Switching to Two Heat-Not-Burn Tobacco Products on Lung Lipid Metabolism in C57BL/6 and Apoe-/- Mice—An Integrative Systems Toxicology Analysis. TOXICOLOGICAL SCIENCES, 149(2): 441–457, 2016	15015_CVD_Resp_ApoE_SW_Pub_Lipid	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\15015_CVD_Resp_ApoE_SW_Pub_Lipid

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Bjoern Titz, Stephanie Boue, Blaine Phillips, Marja Talikka, Terhi Vihervaara, Thomas Schneider, Catherine Nury, Ashraf Elamin, Emmanuel Guedj, Michael J. Peck, Walter K. Schlage, Maciej Cabanski, Patrice Leroy, Gregory Vuillaume, Florian Martin, Nikolai V. Ivanov, Emilija Veljkovic, Kim Ekroos, Reijo Laaksonen, Patrick Vanscheeuwijck, Manuel C. Peitsch, and Julia Hoeng. Supplementary Information Effects of cigarette smoke, cessation and switching to two heat-not-burn tobacco products on lung lipid metabolism in C57BL/6 and Apoe-/- mice – an integrative systems toxicology analysis. TOXICOLOGICAL SCIENCES, 149(2): 441–457, 2016	15015_CVD_Resp_ApoE_SW_Pub_Lipid_SI	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\15015_CVD_Resp_ApoE_SW_Pub_Lipid_SI
Giuseppe Lo Sasso, Bjoern Titz, Catherine Nury, Stéphanie Boué, Blaine Phillips, Vincenzo Belcastro, Thomas Schneider, Sophie Dijon, Karine Baumer, Daruisz Peric, Remi Dulize, Ashraf Elamin, Emmanuel Guedj, Ansgar Buettner, Patrice Leroy, Samuel Kleinhans, Gregory Vuillaume, Emilija Veljkovic, Nikolai V. Ivanov, Florian Martin, Patrick Vanscheeuwijck, Manuel C. Peitsch & Julia Hoeng. Effects of cigarette smoke, cessation and switching to a candidate modified risk tobacco product on the liver in Apoe−/− mice – a systems toxicology analysis. Inhalation Toxicology, 28:5, 226-240, 2016	15015_CVD_Resp_ApoE_SW_Pub_Liver	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\15015_CVD_Resp_ApoE_SW_Pub_Liver
Philip Morris International. Unpublished on file data. Internal Report. Study plan 150082 90 days OECD (+) zurich study genomics approach.	15006_150082 THS SP	7 STUDYANA\75 SYSTOX\InVivo\90dReg\15006_150082 THS SP

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Philip Morris International. Unpublished on file data. Internal Report. Study plan 150083 90 days OECD (+) zurich study proteomics approach, 2013	15006_150083 THS SP	7 STUDYANA\75 SYSTOX\InVivo\90dReg\15006_150083 THS SP
Philip Morris International. Unpublished on file data. Internal Report. Study report 90 day OECD inhalation study on sprague-dawley rats to characterize toxicity of mainstream aerosol from zurich fpd 4.2 cigarettes and comparison to 3R4F mainstream aerosol toxicity study number 15006 part 7 – summary of results for plus group animals.	15006 THS SR Part 7	7 STUDYANA\75 SYSTOX\InVivo\90dReg\ 15006 THS SR Part 7
Philip Morris International. Unpublished on file data. Internal Report. Study report systems toxicological evaluation of THS2.2 90 day inhalation study OECD 413 – OECD plus phase (study number 150082/150083), 2016	15006_150082_150083 THS SR	7 STUDYANA\75 SYSTOX\InVivo\90dReg\ 15006_150082_150083 THS SR
Alain Sewer, Ulrike Kogel, Marja Talikka, Ee Tsin Wong, Florian Martin, Yang Xiang, Emmanuel Guedj, Nikolai Ivanov, Julia Hoeng, Manuel Peitsch. Evaluation of the Tobacco Heating System 2.2 (THS2.2). Part 5: microRNA expression from a 90-day rat inhalation study indicates that exposure to THS 2.2 aerosol causes reduced effects on lung tissue compared with cigarette smoke. Submitted to the journal Regulatory Toxicology and Pharmacology, 2016	15006_150082_150083 THS Pub	7 STUDYANA\75 SYSTOX\InVivo\90dReg\15006_150082_150083 THS Pub

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Full reference	Citation & File name	Filepath
Philip Morris International. Unpublished on file data. Internal Report. Study plan 176500 - 90 days OECD (+) ths2.2.M omics endpoints, 2014	15025_176500 THS SP	7 STUDYANA\75 SYSTOX\InVivo\90dMenth\15025_176500 THS SP
Philip Morris International. Unpublished on file data. Internal Report. Study report 90-day OECD inhalation study on sprague-dawley rats to characterize toxicity of mainstream aerosol from THS2.2 menthol sticks and comparison to mainstream smoke toxicity from 3R4F and dda3 1xmis and dda3 2xmis mentholated combustible cigarettes study number 15025 part 9 – summary of results for plus group animals.	15025 THS SR Part 9	7 STUDYANA\75 SYSTOX\InVivo\90dMenth\15025 THS SR Part 9
Philip Morris International. Unpublished on file data. Internal Report. Study report systems toxicological evaluation of ths2.2 menthol 90 day inhalation study OECD 413 – OECD plus phase (study number 176500), 2016	15025_176500 THS SR	7 STUDYANA\75 SYSTOX\InVivo\90dMenth\15025_176500 THS SR
Ulrike Kogel, Bjoern Titz, Walter K. Schlage, Catherine Nury, Florian Martin, Alberto Oviedo, Stefan Lebrun, Ashraf Elamin, Emmanuel Guedj, Keyur Trivedi, Nikolai V. Ivanov, Patrick Vanscheeuwijck, Manuel C. Peitsch, Julia Hoeng. Evaluation of the Tobacco Heating System 2.2. Part 7: Systems toxicological assessment of a mentholated version revealed reduced cellular and molecular exposure effects compared with mentholated and non-mentholated cigarette smoke. Submitted to the journal Regulatory Toxicology and Pharmacology, 2016	15025_176500 THS Pub	7 STUDYANA\75 SYSTOX\InVivo\90dMenth\15025_176500 THS Pub

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Full reference	Citation & File name	Filepath
Philip Morris International. Unpublished on file data. Internal Report. Application of Systems Pharmacology to Identify Exposure Response Markers in Peripheral Blood after Switching to a Candidate Modified-risk Tobacco Product: The Tobacco Heating System 2.2 (THS 2.2) – REXC 04 and REXA 07 Japan Clinical Studies, 2016	REXA07JP_REXC04JP_1760_1761_SysTox_SR	7 STUDYANA\75 SYSTOX\InVitro\BloodTrans\REXA07JP_REXC04JP_1760_1761_SysTox_SR
Florian Martin, Marja Talikka, Nikolai V. Ivanov, Christelle Haziza, Julia Hoeng, and Manuel C. Peitsch. Application of Systems Pharmacology to Identify Exposure Response Markers in Peripheral Blood after Switching to a Candidate Modified Risk Tobacco Product: The Tobacco Heating System 2.2 (THS 2.2), 2016	REXC03EU_1762_SysTox_Pub	7 STUDYANA\75 SYSTOX\InVitro\BloodTrans\REXC03EU_1762_SysTox_Pub
Philip Morris International. Unpublished on file data. Internal Report. Systems Toxicology – Inflammation	DOC_Inflammation	7 STUDYANA\75 SYSTOX\Supp Docs\DOC_Inflammation
Philip Morris International. Unpublished on file data. Internal Report. Assessment of the exposure responses to 3R4F and THS 2.2 in the context of xenobiotic metabolism	DOC_Xenobiotic_Metabolism	7 STUDYANA\75 SYSTOX\Supp Docs\DOC_Xenobiotic_Metabolism
Philip Morris International. Unpublished on file data. Internal Report. Systems Toxicology – Oxidative Stress.	DOC_Oxidative_stress	7 STUDYANA\75 SYSTOX\Supp Docs\DOC_Oxidative_stress

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Full reference	Citation & File name	Filepath
Philip Morris International. Unpublished on file data. Internal Report. Transversal Document: Lipid Biology.	DOC_Lipid_biology	7 STUDYANA\75 SYSTOX\Supp Docs\DOC_Lipid_Biology
Giuseppe Lo Sasso, Walter K. Schlage, Stéphanie Boue, Emilija Veljkovic, Manuel C. Peitsch, Julia Hoeng. The Apoe−/− mouse model: a suitable model to study cigarette smoke induced cardiovascular and respiratory diseases. Journal of Translational Medicine, 14:146, 2016	15015_CVD_Resp_ApoE _SW_Pub_Model_Justif	7 STUDYANA\75 SYSTOX\InVivo\ApoE-THS-SW\15015_CVD_Resp_ApoE _SW_Pub_Model_Justif
Philip Morris International. Unpublished on file data. Internal Report. Peer review of Data for a modified Risk Tobacco Product (THS2.2, PMI Study Number 15015): Part 1 in Vivo Study – Histopathology Focus, 2016	DOC_ApoE_Ext_Verif_ Histo_Panel	7 STUDYANA\75 SYSTOX\Supp Docs\DOC_ApoE_Ext_Verif_ Histo_Panel
Philip Morris International. Unpublished on file data. Internal Report. Peer review of Data for a modified Risk Tobacco Product (THS2.2, PMI Study Number 15015): Part 2 in Vivo Study – Mixed Expertise, 2016	DOC_ApoE_Ext_Verif_ Mixed_Panel	7 STUDYANA\75 SYSTOX\Supp Docs\DOC_ApoE_Ext_Verif_ Mixed_Panel
Philip Morris International. Unpublished on file data. Internal Report. Peer review of Data for a modified Risk Tobacco Product (THS2.2, PMI Study Number 15015, 1722, 1743): Part 3 in Vivo and In Vitro studies, 2016	DOC_ApoE_Organo_Ext_ Verif_ Mixed_Panel	7 STUDYANA\75 SYSTOX\Supp Docs\DOC_ApoE_Organo_Ext _Verif_Mixed_Panel

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