

2022 年第 11 次第三人體試驗委員會會議記錄

2022year 11th-C IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2022 年 11 月 24 日（星期四）

二、時間 Time：12:00-14:01

三、地點 Location：蘭醫師大樓 B1 尊榮 B 廳 / Webex

四、主席 Chairperson：

顏旭亨（院內、醫療、醫師、男性）

Yen, Hsu-Heng (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

出席人員 Attendant：(職稱略 omit title)

■ 曹紹倫（院內、醫療、醫師、男性）

Tsao, Shao-Lun (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

■ 高峻凱（院內、醫療、醫師、男性）

Kao, Jun-Kai (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

■ 倪亭淵(院內、醫療、醫師、女性)

Ni, Ting-Yuan (Affiliation with Institution, Medical Personnel (Scientific member), doctor, female)

■ 高小玲（院內、醫療、公衛/統計、女性）

Kao, Hsiao-Ling (Affiliation with Institution, Medical Personnel (Scientific member), Member of society, female)

■ 蔡忠融（院外、醫療、公衛/統計、男性）

Tsai, Chung-Jung (non-Affiliation with Institution, Medical Personnel (Scientific member), Epidemiology/ Statistics, male)

■ 洪婉純（院內、非醫療、社工、女性）

Hung, Wan-Chun (Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Social Worker, female)

■ 陳明鋒(院內、非醫療、法律專業、男性)【熟稔易受傷害族群-限制行為能力者 18 至未滿 20 歲未成年人，法律專家】

Chen, Ming-Fong (Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Law, male)

■ 龔心怡（院外、非醫療、社會公正人士、女性）

Kung, Hsin-Yi (non-Affiliation with Institution, Nonmedical Personnel (Scientific member), Member of society, female)

■ 蕭玲玲（院外、非醫療、家庭主婦、女性）

Hsiao, Ling-Ling (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, female)

■ 吳姿慧(院外、非醫療、家庭主婦、女性)

Wu, Tzu-Hui (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, female)

	人數 Persons	備註 Remark
醫療 Medical Personnel	6	醫師(4)、藥師(0)、統計(2) Doctor (4), Pharmacist (0), Statistics (2)
非醫療 Nonmedical Personnel	5	社工(1)、法律(1)、社會公正人士(3) Social Worker (1), Law (1), Member of society (3)
科學 Scientific member	7	醫師(4)、藥師(0)、統計(2)、社會公正人士(1) Doctor (4), Pharmacist (0), Statistics (2), Member of society (1)
非科學 non-Scientific member	4	社工(1)、法律(1)、社會公正人士(2) Social Worker (1), Law (1), Member of society (2)
男 Male	5	院內(4)、院外(1) Affiliation with Institution (4), non-Affiliation with Institution (1)
女 Female	6	院內(3)、院外(3) Affiliation with Institution (3), non-Affiliation with Institution (3)

備註：① 依據「人體研究法」第七條：審查會應置委員五人以上，包含法律專家及其他社會公正人士；研究機構以外人士應達五分之二以上；任一性別不得低於三分之一。審查會開會時，得邀請研究計畫相關領域專家，或研究對象所屬特定群體之代表列席陳述意見。

Remark: (According to Article 7 of Human Body Research Law, the review board shall comprise of at least 5 board members, including legal experts and other impartial citizens. More than two-fifths of the board members shall be persons not affiliated with the research institution and either of the genders shall not account for less than one-third of the board. Experts in the field related to the study protocol or representatives of the special population in the study shall be invited to attend review board meetings and voice their opinions.

- ② 依據「人體研究倫理審查委員會組織及運作管理辦法」第六條：審查會召開一般程序審查會議時，其出席委員應包括機構外之非具生物醫學科學背景委員一人以上。五人以上，不足七人之審查會，應有三分之二以上之委員出席；七人以上之審查會，應有半數以上之委員出席，始得開會。出席委員均為單一性別時，不得進行會議。
- ② According to Article 6 of “The Organization and Operation of Human Research Ethics Review Board,” attendees of the general board meetings shall include more than 1 board member who is not affiliated with the institution and who does not have biomedical background. For review boards of more than 5 members and less than 7 members, more than two-thirds of the members shall attend the meetings. For review boards of more than 7 members, the meeting shall only start if more than half of the members are present. If all the attendees are of the similar gender, the meeting shall not be conducted.

列席人員 Presenting staff：(職稱略 omit title)

- 黃淑萍 (IRB 秘書) Ng Sock Ping (IRB secretary)
- 葉正吉 (IRB 行政人員) Yeh, Cheng Chi (IRB staff)
- 林巧芸 (IRB 行政人員) Lin, Ciao Yun (IRB staff)
- 洪翠霞 (IRB 行政人員) Hung, Tsui-Hsia (IRB staff)
- 李欣儀 (IRB 行政人員) Li, Hsin-Yi (IRB staff)

請 假 Leave：(職稱略 omit title)

- 蔡佩凌 (院外、醫療、藥師、女性)
Tsai, Pei-Ling (non-Affiliation with Institution, Medical Personnel (Scientific member), Pharmacist, female)

缺 席 Absence：(職稱略 omit title)

記 錄 Recorder：洪翠霞 Hung, Tsui-Hsia (IRB staff)

五、會議內容 Meeting：

(一) 討論議案 (議案主題及決議) Discussion (theme and decision)

主題	計畫名稱	決議
編號：221111 【新案】 主持人：李城忠	生物訊息膝套對緩解膝關節疼痛之成效	修正後提會
編號：221112 【新案】	一項前瞻性、隨機分配、雙盲、安慰劑對照、多中心、第 IIb 期試驗，針對接受異體造血幹細胞	修正後複審

主持人：賴冠銘	移植(HSCT)的成人急性骨髓性白血病(AML)病患，評估 mocravimod 作為輔助及維持治療之療效及安全性	
編號：190406 【變更案第 8 次】 主持人：杜思德	第二型糖尿病患者的 Semaglutide 心血管結果試驗 (SOUL)	核准
編號：210607 【變更案第 2 次】 主持人：游欣亭	米糠對非酒精性脂肪肝疾病飲食輔助治療效果	修正後複審
編號：171205 【期中報告第 5 次】 主持人：賴冠銘	一項第三期、隨機分配、開放性、多中心試驗，針對新診斷出多發性骨髓瘤且不符合移植資格的患者，評估 isatuximab (SAR650984)併用 bortezomib (VelcadeR)、lenalidomide 和 dexamethasone 治療相較於 bortezomib 併用 lenalidomide 和 dexamethasone 治療的臨床效益	修正後複審
編號：201212 【期中報告第 2 次】 主持人：陳穆寬	探討 RORB 基因調控口腔癌轉移之機制	修正後複審
編號：211023 【期中報告第 1 次】 主持人：邱怡貞	中風患者健康識能對個案復健的影響	修正後複審
編號：201006 【不遵從事件】 202210-10 主持人：林進清	一項第三期、隨機分配、雙盲、安慰劑對照、多國多中心試驗，評估 Durvalumab 合併確定性化學放射療法用於局部晚期、無法手術切除的食道鱗狀細胞癌之患者(KUNLUN)	存查，同意試驗繼續進行

(二) 已通過之初審案(簡易審查) Report the approved protocol by expedited review

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
1	220623	呼吸照護中心呼吸器依賴與有無血液透析病人呼吸器脫離相關因子之探討 Determining Factors for Successful Weaning of Patients with ventilator dependence and with or without Haemodialysis in a Respiratory Care Center.	吳鳳美 Wu Feng Mei	(略) (N/A)	(略) (N/A)
2	220817	Covid-19 對兒童闌尾炎的影響 The effect of COVID-19 pandemic on pediatric appendicitis	錢大維 Tai Wai Chin	(略) (N/A)	(略) (N/A)

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
3	220913	以手掌及足板症候群表現的急性橋腦梗塞並伴有心室尖端血栓 Acute pontine infarction with apical thrombus manifested by Cheiro-Pedal Syndrome	陳彥宇 Yen-Yu Chen	(略) (N/A)	(略) (N/A)
4	220927	實證學術能力納入醫院基層護理人員專業能力進階制度執行現況之探討(含困境) Explore the Implementation and the Predicaments on the Nurses' Clinical Ladder System of the Hospital by Evidence-Based Academic Competence	李雅文 YA-WEN LEE	(略) (N/A)	(略) (N/A)

(三) 報告已核准之變更案(簡易審查) Report the approved amendment by expedited review

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
1	201210 【第 6 次】	一項第 2b 期、隨機分配、雙盲、安慰劑對照試驗，評估 EDP-938 對於上呼吸道急性感染呼吸道融合病毒的造血細胞移植接受者的作用 A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Effects of EDP-938 in Hematopoietic Cell Transplant Recipients with Acute Respiratory Syncytial Virus Infection of the Upper Respiratory Tract	賴冠銘 KuanMing Lai	(略) (N/A)	(略) (N/A)
2	201220 【第 2 次】	胃癌中谷氨酸運輸蛋白 SLC25A22 在表觀遺傳機制及治療角色之研究 A study of the role of glutamate transporter, SLC25A22, in the epigenetic machinery and treatment of gastric cancer	林淑惠 Shu Hui Lin	(略) (N/A)	(略) (N/A)
3	211013 【第 1 次】	台灣使用巴拉刈自殺之分析與防治策略研究 Suicide by paraquat poisoning in Taiwan and potential prevention strategies	陳力源 Li-Yuan Chen	(略) (N/A)	(略) (N/A)
4	220115 【第 1 次】	建立先天性血栓症之生醫場效應電晶體分子檢測平台及臨床與分子遺傳分析 Development of Silicon Nanowire FET Biosensor platform and Clinical-genetic analysis of families with hereditary thrombophilia	石宇閔 YuHung Shih	(略) (N/A)	(略) (N/A)

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
5	220330 【第 1 次】	早期親職敏感性介入於早產兒母親依附關係、養育信心及親職壓力之成效 The Effectiveness of Early Parental Sensitivity Intervention on attachment, parenting confidence and parental stress of preterm infant mothers	許婷貽 Ting-Yi Hsu	(略) (N/A)	(略) (N/A)

(四) 報告已核准之期中報告(簡易審查) Report the approved interim report by expedited review

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medical primary reviewer
1	151004 【第 7 次】	術中放射線治療應用於台灣婦女乳癌的回溯性分析及前瞻性研究 Intra-operative radiotherapy in the treatment of Taiwanese women with breast cancer- Retrospective analysis and prospective study.	賴鴻文 Hung Wen Lai	(略) (N/A)	(略) (N/A)
2	180905 【第 4 次】	建構急重難感染症功能性蛋白質體平台:早期診斷與適當病患挑選與治療效果預測 Establish functional proteomics platforms for infectious diseases on early diagnosis, patients stratification, predictive treatment.	陳昶華 chen changhua	(略) (N/A)	(略) (N/A)
3	220117 【第 1 次】	彰化基督教醫院胃黏膜下腫瘤的患者行微創手術治療方法的比較 Different Approach of Minimal Invasive Surgery for Gastric Subepithelial Tumor from A Single-Center Experience	林國華 Lin kuo hua	(略) (N/A)	(略) (N/A)
4	220120 【第 1 次】	彰化基督教醫院結石性膽管炎及膽囊炎的患者行內視鏡逆行性膽胰管造影術或腹腔鏡手術治療的成果 Comparison of Outcomes between Endoscopic Retrograde Cholangio-Pancreatography (ERCP) and Laparoscopic Surgery for Calculous Cholangitis and Cholecystitis from A Single-Center Experience	林國華 Lin kuo hua	(略) (N/A)	(略) (N/A)

(五) 報告已存查之結案報告 Report the final report for reference

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	非醫療主審 Non-Medic al primary reviewer
1	161206	一項隨機分配、多中心、開放性、第三期臨床試驗，評估無抗體的 A 型血友病患者接受 Emicizumab 預防性治療，相較於無預防性治療之療效、安全性和藥物動力學 A RANDOMIZED, MULTICENTER, OPEN-LABEL, PHASE III CLINICAL TRIAL TO EVALUATE THE EFFICACY, SAFETY, AND PHARMACOKINETICS OF PROPHYLACTIC EMICIZUMAB VERSUS NO PROPHYLAXIS IN HEMOPHILIA A PATIENTS WITHOUT INHIBITORS	沈銘鏡 Ming Ching Shen	(略) (N/A)	(略) (N/A)
2	200720	用卷積神經網路於電腦斷層肺結節輔助診斷 Computer-aided diagnosis of pulmonary nodules using convolutional neural network	王秉彥 Wang Bing Yen	(略) (N/A)	(略) (N/A)
3	210712	肺阻塞控制概念之驗證及與肺阻塞控制狀態變化相關因素分析 Validation concept of COPD control and the risk factor related to changing in control status.	林慶雄 Ching Hsiung Lin	(略) (N/A)	(略) (N/A)
4	210715	羊水栓塞：跨多科團隊參與的良好結果病例報告 Amniotic fluid embolism: a case report of good outcome with multidiscipline team involvement	吳信宏 Hsinhung Wu	(略) (N/A)	(略) (N/A)
5	210805	探討中部某教學醫院非計畫性 72 小時重返兒童急診之相關因素 Exploring the factors for the unplanned return visits to a hospital's pediatric emergency department within 72 hours in Central Taiwan	劉佩琪 Pei-Chi LIU	(略) (N/A)	(略) (N/A)
6	211025	彰化基督教醫院對於接受肝臟移植的病人長期術後追蹤之併發症與後續治療的研究討論 Post operative complications and managements during Long Term Follow up of Patients with Liver Transplantation in CCH	溫梓丞 Tzu-Cheng Wen	(略) (N/A)	(略) (N/A)

(六) 報告已存查之暫停報告 Report the terminated protocol (無 None)

(七) 報告已存查之終止報告 Report the terminated protocol

序號 No.	IRB 編號 IRB No.	計畫名稱 Protocol title	主持人 PI	醫療主審 Medical primary reviewer	審查結果 Review result
1	201012	傷口癒合及疤痕照護整體研究 Holistic study on wound healing and scar care	林士隆 ShihLung Lin	(略) (N/A)	存查 File for reference
☞終止原因： 主持人要求					
2	210608	輕微局部的子宮肌腺症導致一年輕未生育婦女大量自發性腹內出血：案例報告 Mild focal adenomyosis causing massive spontaneous hemoperitoneum in a young, nongravid woman: a case report	吳信宏 Hsinhung Wu	(略) (N/A)	存查 File for reference
☞終止原因： 單一案例報告，但受試者連繫時同意，但一直沒回診簽署受試者同意書。					

(八) 報告已存查之撤案報告 Report the withdraw protocol (無 None)

(九) 報告已核准之國衛院/ JIRB/ C-IRB/ NRPB Report the ratify protocol that was approved by NHRI/ JIRB/ C-IRB/ NRPB

序號 No.	IRB 編號 IRB No.	國衛院/ JIRB/ C-IRB/ NRPB 編號	階段次數	主持人 PI
		NHRI/ JIRB/ C-IRB/ NRPB protocol No.	Stage	
計畫名稱 Protocol title				
1	221010	【CIRB】111CIRB07130	新案 複審第 1 次	林聖皓 Sheng-Hao Lin
一項隨機分配、開放性、第 3 期試驗，對於未帶有上皮細胞生長因子受體或間變性淋巴瘤激西每基因體腫瘤變異的轉移性非小細胞肺癌患者，評估以 Zimberelimab 和 Domvanalimab 加上化療相較於 Pembrolizumab 加上化療作為第一線治療 A Randomized, Open-Label, Phase 3 Study to Evaluate Zimberelimab and Domvanalimab in Combination with Chemotherapy Versus Pembrolizumab with Chemotherapy for the First-Line Treatment of Patients With Metastatic Non-Small Cell Lung Cancer With No Epidermal Growth Factor Receptor or Anaplastic Lymphoma Kinase Genomic Tumor Aberrations				
2	221025	【CIRB】111CIRB06110	新案 初審	林進清 Jin-Ching Lin
一項隨機、雙盲、安慰劑對照、2 組的第三期試驗，針對患有已切除之頭頸部鱗狀細胞癌且有高復發風險及不符合高劑量 cisplatin 使用資格的參與者，評估 xevinapant 與放射治療相較於安慰劑與放射治療對於呈現無疾病存活期改善的療效和安全性 A randomized, double-blind, placebo-controlled, 2-arm Phase III study to assess efficacy and safety of xevinapant and radiotherapy compared to placebo and radiotherapy for demonstrating improvement of disease-free survival in participants with resected squamous cell carcinoma of the head and neck, who are at high risk for relapse and are ineligible for high-dose cisplatin				
3	190906	【CIRB】108CIRB04070	變更案第 6 次 初審	顏旭亨 HsuHeng Yen

					一項第三期、隨機分配、安慰劑對照、雙盲、多中心試驗，評估以 Etrasimod 作為中度至重度活動型潰瘍性結腸炎受試者誘導和維持治療的療效與安全性 A Phase 3, Randomized, Placebo-Controlled, Double-Blind, Multicenter Study to Evaluate the Efficacy and Safety of Etrasimod for Induction and Maintenance Treatment in Subjects with Moderately to Severely Active Ulcerative Colitis
4	201216	【CIRB】109CIRB10190	變更案第 6 次 初審	陳子和 TzeHo Chen	一項第三期、隨機、雙盲試驗，評估在併用輔助性化學治療的情況下(併用或不併用放射線治療)，Pembrolizumab 相較於安慰劑對於接受根治性目的手術後新診斷為高度風險子宮內膜癌的治療(KEYNOTE-B21 / ENGOT-en11 / GOG- 3053)。 A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Adjuvant Chemotherapy With or Without Radiotherapy for the Treatment of Newly Diagnosed High-Risk Endometrial Cancer After Surgery With Curative Intent (KEYNOTE-B21 / ENGOT-en11 / GOG-3053).
5	210410	【CIRB】110CIRB02028	變更案第 7 次 初審	吳建昇 Wu Jian sheng	一項多中心、開放性延伸期試驗，評估 FARICIMAB 用於治療新生血管型老年性黃斑部病變病患的長期安全性和耐受性(AVONELLE-X) A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY AND TOLERABILITY OF FARICIMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION(AVONELLE-X)
6	210612	【CIRB】110CIRB02033	變更案第 4 次 初審	王全正 ChuanCheng Wang	一項三組、隨機、雙盲、主動對照的第二期臨床試驗，評估晚期或轉移性食道鱗狀細胞癌受試者使用 PD1-TIM3 雙特異性抗體 RO7121661 及 PD1-LAG3 雙特異性抗體 RO7247669 相較 nivolumab 之療效 A 3-ARM, RANDOMIZED, BLINDED, ACTIVE-CONTROLLED, PHASE II STUDY OF RO7121661, A PD1-TIM3 BISPECIFIC ANTIBODY AND RO7247669, A PD1-LAG3 BISPECIFIC ANTIBODY, COMPARED WITH NIVOLUMAB IN PARTICIPANTS WITH ADVANCED OR METASTATIC SQUAMOUS CELL CARCINOMA OF THE ESOPHAGUS
7	210915	【CIRB】110CIRB01008	變更案第 2 次 初審	陳穆寬 MuKuan Chen	比較使用 Buparlisib (AN2025) 併用 Paclitaxel、和單獨使用 Paclitaxel 治療復發性或轉移性頭頸部鱗狀細胞癌之 BURAN 試驗 The BURAN Study of Buparlisib (AN2025) In Combination with Paclitaxel Compared to Paclitaxel Alone, in Patients with Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma
8	211002	【CIRB】110CIRB06131	變更案第 4 次 初審	林慶雄 ChingHsiung Lin	一項第二期、隨機分配、雙盲、安慰劑對照試驗，評估 MEDI3506 用於中度至重度慢性阻塞性肺病和慢性支氣管炎受試者的療效、安全性和耐受性 (FRONTIER 4) A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy, Safety and Tolerability of MEDI3506 in Participants with Moderate to Severe Chronic Obstructive Pulmonary Disease and Chronic Bronchitis (FRONTIER 4)
9	220414	【CIRB】110CIRB05114	變更案第 3 次 初審	陳守棟 SHOU TUNG CHEN	

					<p>一項第 III 期、隨機分配、開放性、多中心試驗，針對雌激素受體陽性、第 2 型人類表皮生長因子受體(HER2)陰性的早期乳癌病患，評估輔助性 Giredestrant 相對於醫師選擇的輔助性內分泌單一療法之療效與安全性</p> <p>A PHASE III, RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY EVALUATING THE EFFICACY AND SAFETY OF ADJUVANT GIREDESTRANT COMPARED WITH PHYSICIAN'S CHOICE OF ADJUVANT ENDOCRINE MONOTHERAPY IN PATIENTS WITH ESTROGEN RECEPTOR-POSITIVE, HER2-NEGATIVE EARLY BREAST CANCER</p>
10	220509	【CIRB】111CIRB01003	變更案第 1 次 初審	林炫聿 Hsuan Yu Lin	<p>一項隨機分配、開放性、Eculizumab 和 Ravulizumab 對照試驗，針對目前接受 Eculizumab 或 Ravulizumab 治療的陣發性夜間血紅素尿症患者，評估 Pozelimab 和 Cemdisiran 併用療法的療效與安全性</p> <p>A Randomized, Open-Label, Eculizumab and Ravulizumab Controlled Study to Evaluate the Efficacy and Safety of Pozelimab and Cemdisiran Combination Therapy in Patients with Paroxysmal Nocturnal Hemoglobinuria Who are Currently Treated with Eculizumab or Ravulizumab</p>
11	211204	【CIRB】110CIRB05097	期中報告第 1 次 初審	王士忠 Wang ShihChung	<p>一項針對輸血依賴型 α 型或 β 型海洋性貧血受試者評估 mitapivat 療效和安全性的第三期、雙盲、隨機分配、安慰劑對照、多中心試驗 (ENERGIZE-T)</p> <p>A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in Subjects With Transfusion-Dependent Alpha- or Beta-Thalassemia (ENERGIZE-T)</p>
12	190807	【CIRB】107CIRB10166	結案 初審	陳穆寬 MuKuan Chen	<p>一項第三期、隨機分配、雙組、開放性標示對照試驗，在接受至少兩線療法（其中至少一線須為全身性療法）期間或之後治療失敗或疾病惡化的患者中，比較 ASP-1929 光免疫療法與醫師所選標準照護療法用於治療局部區域性復發性頭頸部鱗狀細胞癌的表現</p> <p>A Phase 3, Randomized, Double-Arm, Open-Label, Controlled Trial of ASP 1929 Photoimmunotherapy Versus Physician's Choice Standard of Care for the Treatment of Locoregional, Recurrent Head and Neck Squamous Cell Carcinoma in Patients Who Have Failed or Progressed on or After at Least Two Lines of Therapy, of Which at Least One Line Must Be Systemic Therapy</p>
13	211002	【CIRB】110CIRB06131	終止 初審	林慶雄 ChingHsiung Lin	<p>一項第二期、隨機分配、雙盲、安慰劑對照試驗，評估 MEDI3506 用於中度至重度慢性阻塞性肺病和慢性支氣管炎受試者的療效、安全性和耐受性 (FRONTIER 4)</p> <p>A Phase II, Randomized, Double-blind, Placebo-controlled Study to Assess the Efficacy, Safety and Tolerability of MEDI3506 in Participants with Moderate to Severe Chronic Obstructive Pulmonary Disease and Chronic Bronchitis (FRONTIER 4)</p>