

2022 年第 7 次第二人體試驗委員會會議記錄

2022 year 7th-B IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2022 年 07 月 22 日（星期五）

二、時間 Time：12:28-14:05

三、地點 Location：蘭醫師大樓 B1 尊榮 B 廳 / Webex

四、主席 Chairperson：

劉森永(院內、醫療、醫師、男性)

Liu, Sen-Yung (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

出席人員 Attendant：(職稱略 omit title)

■ 楊爵閣(院內、醫療、統計、男性)

Yang, Chueh-Ko (Affiliation with Institution, Medical Personnel (Scientific member), statistics, male)

■ 陳琬青(院內、醫療、醫師、女性)

Chen, Wan-Chin (Affiliation with Institution, Medical Personnel (Scientific member), doctor, female)

■ 陳彥宇(院內、醫療、醫師、男性)

Chen, Yen-Yu (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

【IRB 210802 利益迴避-主持人為同部門醫師 IRB 210802 Avoiding conflicts of interest-Physician of the same department】

■ 林逸祥(院內、醫療、藥師、男性)

Lin, Yi-Hsiang (Affiliation with Institution, Medical Personnel (Scientific member), Pharmacist, male)

■ 黃柔婷(院內、非醫療、社工背景、女性)

Hwang, Rour-Ting (Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Social Worker, female)

■ 劉柏毅(院外、醫療、醫師、男性)

Liu, Po-I (non-Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

■ 謝雅惠(院外、醫療、社會人士、女性)

Hsieh, Ya-Hui (non-Affiliation with Institution, Medical Personnel (Scientific member), Member of society, female)

- 陳志東(院外、非醫療、社會人士、男性)
Chen, Chih-Tung (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, male)
- 林倩芸(院外、非醫療、法律專業、女性)
Lin, Chien Yun (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Law, female)
- 王復堯(院外、非醫療、社會人士、男性)
Wang, Fu-Yan (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, male)
- 李吉豐 (院外、非醫療、病友團體代表、男性)
Lee, Chi-Fong (Affiliation with Institution (Wife is CCH employee), Nonmedical Personnel (non-Scientific member), Patient group representative, male)

| | 人數 | 備註 |
|------------------------------|----|---|
| 醫療 Medical Personnel | 7 | 醫師(4)、藥師(1)、統計(1)、社會人士(1) doctor (4) , Pharmacist (1) , Statistics (1), Member of society(1) |
| 非醫療 Nonmedical Personnel | 5 | 社會人士(3)、法律(1)、病友團體代表(1) Member of society (3) , Law(1), Patient group representative(1) |
| 科學 Scientific member | 7 | 醫師(4)、藥師(1)、統計(1)、社會人士(1) doctor (4) , Pharmacist (1) , Statistics (1), Member of society(1) |
| 非科學 non-Scientific member | 5 | 社會人士(3)、法律(1)、病友團體代表(1) Member of society (3) , Law(1), Patient group representative(1) |
| 男 male | 8 | 院內(4)、院外(4) Affiliation with Institution (5) , non-Affiliation with Institution (3) |
| 女 female | 4 | 院內(2)、院外(2) Affiliation with Institution (2) , non-Affiliation with Institution (2) |

備註 Remarks :

- 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。According to Article 7 of the “Human Subjects Research Act:” “The IRB shall consist of five or more members, including legal expert and other persons of disinterested community members; more than two-fifths shall not be affiliated with the research entity; and no gender shall constitute less than one-third. During IRB meetings, the IRB may invite the attendance of experts familiar with the research field, or representatives of any appropriate group affiliated with the human subjects, to attend and provide comments.”
- 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。According to Article 6 of the “Standards and Operational Guidance for Ethics Review of Human Subject Research:” “Members present at routine review sessions should include at least one with non-biomedical or science background. Two-thirds of entire member should be present for boards with more than 5 and less than 7 members; half of the entire member should be present for boards with more than 7 members before the meeting is commenced. The meeting may not be commenced if the attendee are of the same gender.”

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

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

請 假 Leave：(職稱略 omit title)

缺 席 Absence：(職稱略 omit title)

記 錄 Recorder：林巧芸 Lin, Ciao Yun

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：220513 【新案 複審第 1 次】 主持人：林晏任 | 在外傷病人利用新型電化學免疫檢測器早期偵測內出血 | 核准 |
| 編號：220528 【新案 複審第 1 次】 主持人：張麗君 | 運動及營養自我管理支持措施對改善肺癌癌症惡病質症候群病人營養狀況的效益：隨機分派臨床研究 | 修正後複審 |
| 編號：220634 【新案】 主持人：馬國欽 | 母血中胎兒細胞相對數量與孕婦及胎兒狀況之相關性分析 | 修正後提會 |
| 編號：210802 【期中報告第 1 次】 主持人：吳鴻明 | 探討芳香環轉化西每抑制劑 letrozole 在乳癌輔助治療中引起代謝不良反應的危險因子 | 核准 |
| 編號：210220 【結案 複審第 2 次】 主持人：辜莉絲 | 結腸直腸癌病人存活期症狀困擾、害怕癌症復發之相關性探討 | 存查 |
| 編號：210220 【不遵從事件】 2022-02-15 回覆 1 次 202202-10 主持人：辜莉絲 | 結腸直腸癌病人存活期症狀困擾、害怕癌症復發之相關性探討 | 存查，同意試驗繼續進行 |
| 編號：210310 【不遵從事件】 202206-2 主持人：沈銘鏡 | 一項第 3b 期、單組、開放性試驗，評估 BMN 270 （以腺相關病毒為載體介導基因轉移人類第八凝血因子）與預防性皮質類固醇用於 A 型血友病患者之療效和安全性 | 存查，同意試驗繼續進行 |
| 編號：211110 【不遵從事件】 202206-4 主持人：邱炳芳 | 一項隨機分配、雙盲、安慰劑對照、平行組別、多中心的第 3 期試驗，針對非糖尿病慢性腎臟病患，研究使用標準照護加上 FInerenone 治療腎臟疾病惡化的療效和安全性 | 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 | 220510 | 骨質疏鬆症相關髖部骨折的經濟負擔：單一醫療中心回顧性成本分析 Economic burden of osteoporosis-related hip fracture : A Single Medical Center Retrospective Cost Analysis. | 張櫻霖 Chang Ing Lin | (略) (N/A) | (略) (N/A) |
| 2 | 220514 | 肺囊蟲肺炎(pneumocystis jirovecii pneumonia, PJP)感染之風險及其預後 Risk and prognosis of pneumocystis jirovecii pneumonia (PJP) infection | 黃國揚 Kuo-Yang Huang | (略) (N/A) | (略) (N/A) |
| 3 | 220515 | 一項觀察性研究，針對實行 SABA 挑戰環境後的氣喘患者，評估緩解治療處方型態對保健資源利用與氣喘相關醫療費用造成之變化(ASPIRE) An Observational Study Evaluating Changes in Prescription Patterns of Reliever Therapy on Healthcare Resource Utilization and Asthma-Related Medical Cost in Asthma Patients after the Implementation of a SABA-Challenged Environment (ASPIRE) | 林慶雄 Ching Hsiung Lin | (略) (N/A) | (略) (N/A) |
| 4 | 220604 | 經椎間孔硬脊膜外腔止痛導管置放-病例報告 Transforaminal lumbar epidural catheter misplacement:A case report | 孫盟勝 Sun Meng sheng | (略) (N/A) | (略) (N/A) |
| 5 | 220608 | 血液單核細胞計數與 COPD 惡化的非線性關係 Nonlinear association of blood monocyte counts with exacerbation COPD | 林慶雄 Ching Hsiung Lin | (略) (N/A) | (略) (N/A) |
| 6 | 220613 | 漸進性纖維化間質性肺病疾病組成、發生風險及預後分析 Disease composition and outcome analysis of progressive fibrotic interstitial lung diseases | 林俊維 Chun-Wei Lin | (略) (N/A) | (略) (N/A) |
| 7 | 220616 | 擴展 UTAUT 2 探討臨床護理人員採用醫療人工智慧系統前因 Extend UTAUT 2 to explore the antecedents of nursing staff adoption of medical artificial intelligence systems | 林玉皎 Lin Yu Chiao | (略) (N/A) | (略) (N/A) |
| 8 | 220629 【免審】 | 探討 11-dehydrosinulariolid 於治療特發性肺纖維化之應用 Study the Effects of 11-dehydrosinulariolid in Treating Idiopathic Pulmonary Fibrosis | 林聖皓 Sheng Hao Lin | (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 |
|-----------|-------------------|--|----------------------------|--|---|
| 9 | 220701 | 建置門診大腸鏡檢查或處置非計畫性 72 小時內返回急診留觀或住院主動通知機制改善大腸鏡併發症處置成效 Establish an automatically notifying mechanism for caregivers to improve the complication treatment effects of unexpected hospitalization within 72 hours of outpatient colonoscopies. | 林慶雄 Ching Hsiung Lin | (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 | 201242 【第 2 次】 | 乳房微創切除手術(內視鏡及機器手臂)於早期乳癌患者之應用之多中心研究 Patients with early stage breast cancer managed by R-NSM, conventional NSM (C-NSM) or E-NSM breast surgery was retrospectively and prospectively collected and analyzed from multi-centers in Taiwan. | 賴鴻文 Hung Wen Lai | (略) (N/A) | (略) (N/A) |
| 2 | 210310 【第 4 次】 | 一項第 3b 期、單組、開放性試驗，評估 BMN 270 (以腺相關病毒為載體介導基因轉移人類第八凝血因子) 與預防性皮質類固醇用於 A 型血友病患者之療效和安全性 A Phase 3b, Single Arm, Open-Label Study to Evaluate the Efficacy and Safety of BMN 270, an Adeno-Associated Virus Vector-Mediated Gene Transfer of Human Factor VIII, with Prophylactic Corticosteroids in Hemophilia A Patients | 沈銘鏡 Ming Ching Shen | (略) (N/A) | (略) (N/A) |
| 3 | 210719 【第 2 次】 | 胸腔 X 光之結節偵測人工智慧輔助系統模型開發 Chest X ray nodule AI assisted detection model development | 黃國揚 Kuo-Yang Huang | (略) (N/A) | (略) (N/A) |
| 4 | 211114 【第 4 次】 | 評估 Marstacimab 預防性治療帶有或未帶有抑制抗體之重度 (凝血因子活性 < 1%) A 型血友病參與者或帶有或未帶有抑制抗體之中重度至重度 B 型血友病參與者 (凝血因子活性 > 2%) 長期安全性、耐受性和療效的一項開放性延伸試驗 | 沈銘鏡 Ming Ching Shen | (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 |
|-----------|-------------------|---|--------------------|--|---|
| | | An Open-Label Extension Study to Evaluate the Long-Term Safety, Tolerability, and Efficacy of Marstacimab Prophylaxis in Severe (Coagulation Factor Activity <1%) Hemophilia A Participants With or Without Inhibitors or Moderately Severe to Severe Hemophilia B Participants (Coagulation Factor Activity ?2%) With or Without Inhibitors. | | | |
| 5 | 220109 【第 1 次】 | 第三孕期婦女及其配偶之睡眠品質、成人依附情感之相關性探討 The Correlation in Sleep Quality and Adult Attachment on Third-trimester Women and Their Partners. | 李心慈 Li Hsin Tzu | (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 | 150610 【第 7 次】 | 正子掃描在肺癌成效 The performance of PET for lung cancer | 張柏齡 Chang Po Ling | (略) (N/A) | (略) (N/A) |
| 2 | 200213 【第 2 次】 | 2020 年台灣腎臟切片病理登錄系統 Registration of pathological report of kidney biopsy in Taiwan 2020 | 邱炳芳 Ping Fang Chiu | (略) (N/A) | (略) (N/A) |
| 3 | 200616 【第 2 次】 | 一項隨機分配、開放性、多中心的第 III 期臨床試驗，評估 Toripalimab (JS001) 併用 Bevacizumab 相較於 Sorafenib 作為晚期肝細胞癌(HCC)第一線治療的安全性和療效 A randomized, open-label, multi-center phase III clinical study to evaluate the safety and efficacy of Toripalimab (JS001) combined with Bevacizumab versus Sorafenib as first-line therapy for advanced hepatocellular carcinoma (HCC) | 蘇維文 Wei Wen Su | (略) (N/A) | (略) (N/A) |
| 4 | 210417 【第 1 次】 | 建立臺灣重要微生物抗藥性與抗微生物製劑使用主動監測網 Building an active surveillance network of important Microbiologic and anti-microbial resistance in Taiwan | 李育霖 LI YU LIN | (略) (N/A) | (略) (N/A) |
| 5 | 210817 | 以人工智慧輔助診斷胸部外傷之電腦斷層 | 黃章倫 | (略) | (略) |

| 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 |
|-----------|-------------------|---|--------------------|--|---|
| | 【第 1 次】 | 影像 Application of artificial intelligence to assist CT diagnosis of thoracic trauma | Chang Lun Huang | (N/A) | (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-Medical primary reviewer |
|-----------|-------------------|---|---------------------------|--|---|
| 1 | 150610 【第 7 次】 | 正子掃描在肺癌成效 The performance of PET for lung cancer | 張柏齡 Chang Po Ling | (略) (N/A) | (略) (N/A) |
| 2 | 200213 【第 2 次】 | 2020 年台灣腎臟切片病理登錄系統 Registration of pathological report of kidney biopsy in Taiwan 2020 | 邱炳芳 Ping Fang Chiu | (略) (N/A) | (略) (N/A) |
| 3 | 200616 【第 2 次】 | 一項隨機分配、開放性、多中心的第 III 期 臨床試驗，評估 Toripalimab (JS001) 併用 Bevacizumab 相較於 Sorafenib 作為晚期肝 細胞癌(HCC)第一線治療的安全性和療效 A randomized, open-label, multi-center phase III clinical study to evaluate the safety and efficacy of Toripalimab (JS001) combined with Bevacizumab versus Sorafenib as first-line therapy for advanced hepatocellular carcinoma (HCC) | 蘇維文 Wei Wen Su | (略) (N/A) | (略) (N/A) |
| 4 | 210417 【第 1 次】 | 建立臺灣重要微生物抗藥性與抗微生物製 劑使用主動監測網 Building an active surveillance network of important Microbiologic and anti-microbial resistance in Taiwan | 李育霖 LI YU LIN | (略) (N/A) | (略) (N/A) |
| 5 | 210817 【第 1 次】 | 以人工智慧輔助診斷胸部外傷之電腦斷層 影像 Application of artificial intelligence to assist CT diagnosis of thoracic trauma | 黃章倫 Chang Lun Huang | (略) (N/A) | (略) (N/A) |

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

| 序號 | IRB 編號 | 計畫名稱 | 主持人 | 醫療主審 | 審查結果 |
|----|--------|--|-----------------------|--------------|-----------------------------|
| 1 | 210809 | COVID-19 通報個案於急診採檢之流行病學與預 後分析 Epidemiological and prognostic analysis of COVID-19 reported cases in emergency department | 林晏任 Lin Yan Ren | (略) (N/A) | 存查 File for reference |

☞終止原因： 疫情影響研究進度，且經費不足，故先申請終止。

(七) 報告已存查之暫停報告 Report the suspended protocol (無 None)

(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 NHRI/ JIRB/ C-IRB/ NRPB protocol No. | 階段次數 Stage | 主持人 PI |
|--|-------------------|---|---------------|------------------------|
| 計畫名稱 Protocol title | | | | |
| 1 | 220622 | 【NIRB】EC1101006-E | 新案 初審 | 王全正 ChuanCheng Wang |
| 一合併使用癌必定(cabozantinib)及舒得寧(lanreotide)針對標靶藥物或化療失敗之晚期胃腸胰神經內分泌瘤之一、二期臨床試驗 A Phase I/II Study Using Cabozantinib and Lanreotide as Treatment for Advanced Gastroenteropancreatic Neuroendocrine Tumors That Failed Molecular Targeted Therapies or Chemotherapy (SCALET) | | | | |
| 2 | 220705 | 【CIRB】111CIRB05088 | 新案 初審 | 林聖皓 Sheng Hao Lin |
| 一項第三期、開放性、隨機分配試驗，比較 Lazertinib 併用人工皮下注射 Amivantamab 相較於靜脈輸注 Amivantamab 或經皮下給藥系統之 Amivantamab，針對曾接受 Osimertinib 及化學治療後惡化具有 EGFR 突變之晚期或轉移性非小細胞肺癌患者 A Phase 3, Open-label, Randomized Study of Lazertinib with Subcutaneous Amivantamab Administered via Manual Injection Compared with Intravenous Amivantamab or Amivantamab Subcutaneous On Body Delivery System in Patients with EGFR-mutated Advanced or Metastatic Non-small Cell Lung Cancer After Progression on Osimertinib and Chemotherapy | | | | |
| 3 | 200417 | 【CIRB】109CIRB02010 | 變更案第 7 次 初審 | 杜思德 Tu shih te |
| Tirzepatide 相較於 Dulaglutide 對第 2 型糖尿病患者之嚴重心血管不良事件的成效 (SURPASS-CVOT) The Effect of Tirzepatide versus Dulaglutide on Major Adverse Cardiovascular Events in Patients with Type 2 Diabetes (SURPASS-CVOT) | | | | |
| 4 | 200517 | 【CIRB】108CIRB07115 | 變更案第 6 次 初審 | 蘇維文 Wei Wen Su |
| 一項第二期、隨機分配、適應性、開放性平台試驗，評估多重併用療法使用於慢性 B 型肝炎參與者的療效與安全性 APHASE II, RANDOMISED, ADAPTIVE, OPEN-LABEL PLATFORM TRIAL TO EVALUATE EFFICACY AND SAFETY OF MULTIPLE COMBINATION THERAPIES IN PARTICIPANTS WITH CHRONIC HEPATITIS B | | | | |
| 5 | 200615 | 【CIRB】109CIRB02015 | 變更案第 5 次 初審 | 王文甫 Wenfu Wang |

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| | 第三 b 期、開放標示、多中心、評估 BIIB037 (aducanumab) 用於先前參加過 Aducanumab 221AD103, 221AD301, 221AD302 和 221AD205 試驗的阿茲海默症受試者之安全性試驗 Phase 3b Open-Label, Multicenter, Safety Study of BIIB037 (aducanumab) in Subjects With Alzheimer's Disease Who Had Previously Participated in the Aducanumab Studies 221AD103, 221AD301, 221AD302, and 221AD205 | | | |
| 6 | 201005 | 【CIRB】109CIRB08144 | 變更案第 5 次 初審 | 林慶雄 ChingHsiung Lin |
| | 一項隨機分配、雙盲、雙虛擬、平行分組、多中心的 24 至 52 週可變長度試驗，旨在評估 Budesonide、Glycopyrronium 和 Formoterol Fumarate 定量噴霧吸入器 (MDI) 相對於 Budesonide 和 Formoterol Fumarate MDI 和 SymbicortR 壓力式 MDI，對氣喘控制不良的成人和青少年參與者的療效與安全性 (KALOS) A Randomized, Double-Blind, Double Dummy, Parallel Group, Multicenter 24 to 52 Week Variable Length Study to Assess the Efficacy and Safety of Budesonide, Glycopyrronium, and Formoterol Fumarate Metered Dose Inhaler (MDI) Relative to Budesonide and Formoterol Fumarate MDI and SymbicortR Pressurized MDI in Adult and Adolescent Participants with Inadequately Controlled Asthma (KALOS) | | | |
| 7 | 210126 | 【CIRB】109CIRB10193 | 變更案第 3 次 初審 | 陳明 Ming Chen |
| | 一項針對 18 到 49 歲孕婦之第三期、隨機分配、雙盲、安慰劑對照多國研究案，以肌肉注射單劑無佐劑呼吸道融合病毒孕婦疫苗，用以預防其嬰兒出生後至 6 個月感染呼吸道融合病毒相關的下呼吸道疾病，以驗證疫苗的效果 A Phase III, randomized, double-blind, placebo-controlled multi-country study to demonstrate efficacy of a single dose of unadjuvanted RSV Maternal vaccine, administered IM to pregnant women 18 to 49 years of age, for prevention of RSV associated LRTI in their infants up to 6 months of age | | | |
| 8 | 210518 | 【CIRB】110CIRB02031 | 變更案第 3 次 初審 | 林聖皓 Sheng Hao Lin |
| | 一項第 3 期、隨機分配、雙盲試驗，針對從未接受治療、經 PD-L1 表達篩選的且不可切除的局部晚期或轉移性非小細胞肺癌患者，探討 BGB-A1217 (一種抗 TIGIT 抗體) 併用 Tislelizumab 相較於 Pembrolizumab 的作用 A Phase 3, Randomized, Double-Blind Study of BGB-A1217, an Anti-TIGIT Antibody, in Combination With Tislelizumab Compared to Pembrolizumab in Patients With Previously Untreated, PD-L1-Selected, and Locally Advanced, Unresectable, or Metastatic Non-Small Cell Lung Cancer | | | |
| 9 | 210622 | 【CIRB】110CIRB3054 | 變更案第 5 次 初審 | 邱南英 Nan Ying Chiu |
| | 針對持續接受試驗 54135419TRD3013 的 Esketamine 鼻用噴霧治療之難治型重度憂鬱症患者所進行的開放性長期延伸試驗 Open-label Long-Term Extension Study for Participants with Treatment-Resistant Major Depressive Disorder Who are Continuing Esketamine Nasal Spray Treatment From Study 54135419TRD3013 | | | |
| 10 | 211020 | 【CIRB】110CIRB04089 | 變更案第 1 次 初審 | 王百孚 Pai fu Wang |

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| | <p>一項多中心、隨機分配、雙盲、安慰劑對照的第 3 期試驗，比較 Fuzuloparib 合併 Abiraterone Acetate 與 Prednisone (AA-P) 相較於安慰劑合併 AA-P 作為轉移性去勢抗性前列腺癌患者的第一線治療</p> <p>A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase III Study of Fuzuloparib Combined with Abiraterone Acetate and Prednisone (AA-P) versus Placebo Combined with AA-P as First-Line Treatment in Patients with Metastatic Castration-Resistant Prostate Cancer</p> | | | |
| 11 | 211110 | 【CIRB】110CIRB07138 | 變更案第 2 次 初審 | 邱炳芳 Ping Fang Chiu |
| | <p>一項隨機分配、雙盲、安慰劑對照、平行組別、多中心的第 3 期試驗，針對非糖尿病慢性腎臟病患，研究使用標準照護加上 FInerenone 治療腎臟疾病惡化的療效和安全性</p> <p>A randomized, double-blind, placebo-controlled, parallel-group, multicenter Phase 3 study to investigate the efficacy and safety of FInerenone, in addition to standard of care, on the progression of kidney disease in patients with Non-Diabetic Chronic Kidney Disease</p> | | | |
| 12 | 170904 | 【CIRB】106CIRB04073 | 期中報告第 5 次 初審 | 紀炳銓 Bin Chuan Ji |
| | <p>全球性第三期、隨機分配、多中心、開放標記、含對照的臨床試驗，評估 Durvalumab 或 Durvalumab 加上 Tremelimumab 併用含鉑化療，做為轉移性非小細胞肺癌 (NSCLC) 患者的第一線治療 (POSEIDON)</p> <p>A Phase III, Randomized, Multi-Center, Open-Label, Comparative Global Study to Determine the Efficacy of Durvalumab or Durvalumab and Tremelimumab in Combination With Platinum-Based Chemotherapy for First-Line Treatment in Patients With Metastatic Non Small-Cell Lung Cancer (NSCLC) (POSEIDON)</p> | | | |
| 13 | 210703 | 【CIRB】110CIRB03055 | 期中報告第 1 次 複審第 1 次 | 林聖皓 Sheng Hao Lin |
| | <p>LIBRETTO-432：針對確定性局部區域治療 IB-III A 期 RET 融合-非小細胞肺癌(NSCLC)陽性參與者後之 Selpercatinib 輔助治療的一項安慰劑對照、雙盲、第 3 期隨機分配試驗</p> <p>LIBRETTO-432: A Placebo-controlled Double-Blinded Randomized Phase 3 Study of Adjuvant Selpercatinib following Definitive Locoregional Treatment in Participants with Stage IB-III A RET fusion-Positive NSCLC</p> | | | |