

2022 年第 9 次第一人體試驗委員會會議記錄

2022 year 9th-A IRB Meeting Minutes

一、日期 Date(YY/MM/DD)：2022 年 09 月 13 日（星期二）

二、時間 Time：12:00-13:37

三、地點 Location：蘭醫師大樓 B1 尊榮 B 廳 / Teams

四、主席 Chairperson：

蘇矢立（院內、醫療、醫師、男性）

Su, Shih-Li (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

出席人員 Attendant：(職稱略 omit title)

■ 陳書毓（院內、醫療、護理、女性）

Chen, Shu-Yu (Affiliation with Institution, Medical Personnel (Scientific member), Nurse, female)

■ 楊淵博（院內、醫療、醫師、男性）

Yang, Yuan-Po (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

■ 林彥至(院內、醫療、醫師、男性)【IRB 180903 利益迴避-研究計畫協同主持人 IRB 180903 Avoiding conflicts of interest- Co PI】

Lin, Yen Chih (Affiliation with Institution, Medical Personnel (Scientific member), doctor, male)

■ 蕭品卉（院內、醫療、醫師、女性）【IRB 190713 利益迴避-主持人為同部門醫師 IRB 190713 Avoiding conflicts of interest- Physician of the same department】

Hsiao, Yi-Hsuan (Affiliation with Institution, Medical Personnel (Scientific member), doctor, female)

■ 賴穎萱（院內、醫療、藥師、女性）

Lai, Ying-Hsuan (Affiliation with Institution, Medical Personnel (Scientific member), Pharmacist, female)

■ 柯智慧（院內、非醫療、社工、女性）【熟稔易受傷害族群-未成年人（0-12 歲），社工師】

Ko, Chih-Hu (Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Social Worker, female)

■ 倪淑鳳（院外、非醫療、社會公正人士、女性）

Shu-Feng, Ni (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, female)

■ 賴芳足（院外、醫療、公共衛生、女性）

Lai, Fang-Zu (non-Affiliation with Institution, Medical Personnel (Scientific member), Epidemiology/Statistics, female)

- 詹明真（院外、非醫療、法律、女性）【IRB 210325 利益迴避-協同主持人謝承樸醫師為其之配偶 IRB 210325 Avoiding conflicts of interest- The co-PI Cheng Pu Hsieh is her husband】
Chan, Melody (Affiliation with Institution (Husband is CCH employee), Nonmedical Personnel (non-Scientific member), Lawyer, female)
- 林志榮（院外、醫療、公衛/統計、男性）
Lin, Jr-Rung Lin (non-Affiliation with Institution, Medical Personnel (Scientific member), Epidemiology/ Statistics, male)
- 林景釧（院外、非醫療、社會人士、男性）
Lin, Ching-Chuan (non-Affiliation with Institution, Nonmedical Personnel (non-Scientific member), Member of society, male)

| | 人數 | 備註 |
|---------------------------------|----|--|
| 醫療 Medical Personnel | 8 | 醫師(4)、護理(1)、藥師(1)、公共衛生/統計(2)、 doctor (4)、Nurse (1)、Pharmacist (1)、Epidemiology/ Statistics (2) |
| 非醫療 Nonmedical Personnel | 4 | 法律(1)、社工(1)、社會人士(2) Lawyer(1)、Social Worker (1)、Member of society (2) |
| 科學 Scientific member | 8 | 醫師(4)、護理(1)、藥師(1)、公共衛生/統計(2) doctor (4)、Nurse (1)、Pharmacist (1)、Epidemiology/ Statistics (2) |
| 非科學 non-Scientific member | 4 | 法律(1)、社工(1)、社會人士(2) Lawyer(1)、Social Worker (1)、Member of society (2) |
| 男 male | 5 | 院內(3)、院外(2) Affiliation with Institution (3)、non-Affiliation with Institution (2) |
| 女 female | 7 | 院內(4)、院外(3) Affiliation with Institution (5)、non-Affiliation with Institution (2) |

備註：♠ 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 (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)

缺 席 Absence：(職稱略 omit title)

記 錄 Recorder：洪翠霞 Hung, Tsui-Hsia

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：220716 【新案】 簡易審查 主持人：彭于賓 | 玻尿酸組織填充前回抽-透過前置利多卡因針劑增加安全性 | 修正後提會 |
| 編號：220901 【新案】 主持人：林敬業 | 研究重組凝血因子 VIII Fc 融合蛋白(rFVIIIfc)在先前接受過治療的 A 型血友病小孩患者之治療效果 | 修正後複審 |
| 編號：180903 【期中報告第 4 次】 主持人：蘇維文 | C 型肝炎小分子抗病毒藥物治療療效、安全性與長期預後疾病相關之全國性臨床世代研究 | 修正後複審 |
| 編號：180907 【期中報告第 4 次】 主持人：林炫聿 | 一項第 3 期、開放性、隨機分配試驗，針對未接受 ESA 且需要輸注紅血球的受試者，以 IPSS-R 評估為極低、低或中等風險的骨髓增生 | 核准 |

| | | |
|-------------------------------------|--|---------|
| | 不良症候群 (MDS) 引起之貧血，比較使用 Luspatercept (ACE-536) 相較於 Epoetin alfa 的療效及安全性 | |
| 編號：200703 【期中報告第 2 次】 主持人：邱重閔 | 探討中藥 WT 治療第三型小腦萎縮症病人 IGF-1 之臨床研究- 前驅研究 | 修正後複審 |
| 編號：190713 【實地訪視第 1 次】 主持人：陳明 | 台灣精準醫療計畫(II) | 書面說明後複審 |
| 編號：210325 【實地訪視第 1 次】 主持人：林聖皓 | 肺部疾病及骨科肢體病變用可攜式 X 光機產品上市前驗證 | 書面說明後複審 |
| 編號：211116 【實地訪視第 1 次】 主持人：林晏任 | 運用雷射血液循環系統分析休克病患四肢末端血循環之臨床研究 | 書面說明後複審 |
| 編號：211117 【實地訪視第 1 次】 主持人：林晏任 | 以雷射血液循環系統分析病患之傷口周邊血循環之臨床研究 | 通過 |

(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 | 220702 | 以前外排錨釘執行的全新旋轉袖套修補術和肱二頭肌腱固定術之臨床結果 Clinical outcome of a novel 'whole layer' rotator cuff repair technique with all arthroscopic biceps tenodesis using anterolateral suture anchor | 石久煜 Shih Chiu-Yu | (略) (N/A) | (略) (N/A) |
| 2 | 220706 | COVID-19 急診病人之流病及預後分析 Analysis of the epidemic and prognosis of COVID-19 patients in emergency department | 林晏任 Lin Yan Ren | (略) (N/A) | (略) (N/A) |
| 3 | 220711 | 甲狀腺病人眼窩減壓手術後之併發症 Complication after orbital decompression in patient with thyroid orbitopathy | 張丞賢 CHANG CHENG HSIEN | (略) (N/A) | (略) (N/A) |
| 4 | 220804 | 放射線治療對乳癌患者生活品質之影響:以問卷調查患者上肢、肩膀活動度及乳房疼痛為指標。 Impact of radiotherapy on quality-of-life of breast cancer patients: A survey of utility of upper limb, shoulder range of motion, and | 賴鴻文 Hung Wen Lai | (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 |
|-----------|-------------------|--|------------------------|--|---|
| | | pain of breast. | | | |
| 5 | 220810 | 胸腔鏡肺結節手術於術前進行電腦斷層導引線圈定位的定位失敗因子分析 Analysis of marking failure of CT-guided microcoil localization for pulmonary nodules before thoracoscopic surgery | 黃章倫 Chang Lun Huang | (略) (N/A) | (略) (N/A) |
| 6 | 220818 | 探討住院病患使用致跌藥物的跌倒風險與臨床預後的關聯性 Prediction of Falls Risk and Falls Risk Increase Drugs Using Big Data Analysis | 劉森永 SenYung Liu | (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 | 060715 【第 18 次】 | 監測抗生素抗藥性的趨勢研究 Study For Monitoring Antimicrobial Resistance Trends (SMART) | 劉尊榮 Theophile LIU | (略) (N/A) | (略) (N/A) |
| 2 | 190106 【第 2 次】 | 牙周病人牙周組織的 DNA 氧化損傷及粒線體 DNA 質與量的變化之研究 Study on oxidative DNA damage, qualitative and quantitative alterations of mtDNA in the periodontal tissues of patients with periodontitis | 黃瑞彰 Huang Juichang | (略) (N/A) | (略) (N/A) |
| 3 | 210325 【第 4 次】 | 肺部疾病及骨科肢體病變用可攜式 X 光機產品上市前驗證 Pre-market verification of portable X-ray machines for lung diseases and orthopedic limb lesions | 林聖皓 Sheng Hao Lin | (略) (N/A) | (略) (N/A) |
| 4 | 210908 【第 2 次】 | 運用員工健康數據建構機器學習模型預測員工之心血管疾病風險與過負荷風險 Establishment of a machine learning model based on the employees' health database for cardiovascular disease and work overload risk prediction | 劉晏孜 Yen Tze Liu | (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 | 060715 【第 16 次】 | 監測抗生素抗藥性的趨勢研究 Study For Monitoring Antimicrobial Resistance Trends (SMART) | 劉尊榮 Theophile LIU | (略) (N/A) | (略) (N/A) |
| 2 | 180910 【第 4 次】 | 乳癌常規分期掃描之應用 Utility of routine staging scans in breast cancer | 林喆 Che Lin | (略) (N/A) | (略) (N/A) |
| 3 | 200816 【第 2 次】 | 癌症決策支援平台國際示範基地 Oncology Clinical Decision Support Platform Reference Site Program | 林慶雄 Ching Hsiung Lin | (略) (N/A) | (略) (N/A) |
| 4 | 210713 【第 1 次】 | 頸動脈超音波在心房顫動病人急性腦中風 後接受高強度復健之研究 Carotid duplex in acute stroke patients with atrial flutter/fibrillation receiving high intensity rehabilitation | 林志明 Chih Ming Lin | (略) (N/A) | (略) (N/A) |
| 5 | 210806 【第 1 次】 | 電腦斷層血管攝影/電腦斷層血流灌注掃描 參數在急性中大腦動脈缺血性腦中風病人 接受動脈取栓術預測長期預後之研究 The parameters from computed tomographic angiography/computed tomographic perfusion in predicting long term functional outcomes of acute middle cerebral artery ischemic stroke patients receiving intra-arterial thrombectomy treatments | 林志明 Chih Ming Lin | (略) (N/A) | (略) (N/A) |
| 6 | 210902 【第 1 次】 | 運用深度學習方法對主要唾液腺腫瘤的超 音波掃描影像來評估其良性和惡性程度 Using deep learning approach to assessment of benignity and malignancy from the ultrasound scan of patients with major salivary gland tumor | 余萬年 YU WAN NIEN | (略) (N/A) | (略) (N/A) |
| 7 | 210908 【第 1 次】 | 運用員工健康數據建構機器學習模型預測 員工之心血管疾病風險與過負荷風險 Establishment of a machine learning model based on the employees' health database for cardiovascular disease and work overload risk prediction | 劉晏孜 Yen Tze Liu | (略) (N/A) | (略) (N/A) |
| 8 | 210911 【第 1 次】 | 血管炎病患急性梗塞性中風動脈取栓愈後 預測因子分析 Analysis of predictive factors after endovascular thrombectomy in vasculitis patients with acute infarct stroke | 陳彥中 YEN- CHUNG CHEN | (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-Medical primary reviewer |
|-----------|-------------------|--|-------------------------|--|---|
| 1 | 170612 | 帕金森氏症之步態凍結研究 The Comorbidity study of Freezing of Gait in Parkinson Disease. | 巫錫霖 Wu Shey Lin | (略) (N/A) | (略) (N/A) |
| 2 | 181020 | 運用 3D microscope 於肝臟移植手術之適用性評估 Applicability evaluation of 3D microscope for liver transplantation | 林士隆 Shih Lung Lin | (略) (N/A) | (略) (N/A) |
| 3 | 200816 | 癌症決策支援平台國際示範基地 Oncology Clinical Decision Support Platform Reference Site Program | 林慶雄 Ching Hsiung Lin | (略) (N/A) | (略) (N/A) |
| 4 | 201014 | 深度學習根據胸腔 X-光對植入管路的分類和預測 Classification and Prediction of Tube Position in Chest x-ray | 顏旭亨 Hsu Heng Yen | (略) (N/A) | (略) (N/A) |
| 5 | 210610 | 營養照顧對放射治療癌症患者身體組成參數的影響 The Effects of nutritional Care on Body Composition Parameters in Cancer Patients under Radiotherapy | 陳美櫻 Mei-Ying CHEN | (略) (N/A) | (略) (N/A) |
| 6 | 210619 | 以智慧型穿戴裝置初探醫院女性護理師的憂鬱、焦慮及壓力程度與生理指標之關係 A pilot study of applying wearable devices on female nurses to delve into the relationship between their degree of anxiety and vital signs | 簡佑安 Chien, Yu-An | (略) (N/A) | (略) (N/A) |
| 7 | 210807 | 110 年苗栗縣銀髮族失智症相關風險因子調查 A survey for risk factors related to dementia among senior in Miaoli County in 2021 | 黃瑞華 Jui-Hua Huang | (略) (N/A) | (略) (N/A) |
| 8 | 210912 | 不同的社區照護模式對失智症認知功能的影響 The difference of cognitive decline between the community-dwelling dementia patients using different care model | 張凱茗 Jhang Kai Ming | (略) (N/A) | (略) (N/A) |
| 9 | 211006 | 大腦枕葉中風：腺病毒載體新冠疫苗的災難性後遺症 Occipital infarction: A devastating complication after an adenovirus-vector COVID-19 vaccine | 吳建昇 Wu Jian sheng | (略) (N/A) | (略) (N/A) |
| 10 | 211007 | 高度近視併脈絡膜新生血管的形成可以抵抗斑塊狀脈絡膜萎縮 Myopic choroidal neovascularization may confer resistance to patchy chorioretinal atrophy. | 吳建昇 Wu Jian sheng | (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 |
|-----------|-------------------|---|-----------------------|--|---|
| 11 | 220219 | 藥物預測跌倒之風險 Medication Prediction in Fall Risk | 劉森永 SenYung Liu | (略) (N/A) | (略) (N/A) |

(六) 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 | 200734 | 外傷性院前心跳停止病人，相關醫療及社會支出及長期存活情況追蹤 Analysis of related medical and social expenditures and long-term survival in patients with traumatic OHCA | 林晏任 Lin Yan Ren | (略) (N/A) | 存查 File for reference |
| ☞終止原因：因經費不足，申請終止。待日後有充裕經費再繼續進行研究。 | | | | | |
| 2 | 200735 | 早期施打腎上腺素對於低血容誘發之到院前心跳停止器官灌流之預後分析 Analyze the post-resuscitative organ perfusions of first epinephrine treatment among patients with hypovolemic OHCA | 林晏任 Lin Yan Ren | (略) (N/A) | 存查 File for reference |
| ☞終止原因：因經費不足，申請終止。待日後有充裕經費再繼續進行研究。 | | | | | |

(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 |
|--|-------------------|---|---------------|---------------------|
| 1 | 220713 | 【CIRB】111CIRB05089 | 新案 複審第 1 次 | 賴冠銘 KuanMing Lai |
| 一項評估 Amivantamab 單一療法及併用標準照護化療治療晚期或轉移性大腸直腸癌參與者的開放性第 1b/2 期試驗 A Phase 1b/2, Open-Label Study of Amivantamab Monotherapy and in Addition to Standard-of-Care Chemotherapy in Participants with Advanced or Metastatic Colorectal Cancer | | | | |
| 2 | 190317 | 【CIRB】107CIRB12198 | 變更案第 14 次 初審 | 陳子和 TzeHo Chen |

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|---|--------|--------------------|-------------|---|
| | | | | 一項針對 BRCA 無突變之晚期上皮性卵巢癌(EOC)，使用化療併用或不併用 Pembrolizumab 後，以 Olaparib 或安慰劑維持做為第一線治療之隨機分派、第三期雙盲試驗 (KEYLYNK-001 / ENGOT-ov43 / GOG-3036) A Randomized Phase 3, Double-Blind Study of Chemotherapy With or Without Pembrolizumab Followed by Maintenance With Olaparib or Placebo for the First-Line Treatment of BRCA non-mutated Advanced Epithelial Ovarian Cancer (EOC) (KEYLYNK-001 / ENGOT-ov43 / GOG-3036) |
| 3 | 200722 | 【CIRB】109CIRB04054 | 變更案第 7 次 初審 | 夏建勳 Chien Hsun Hsia |
| | | | | 一項多中心、隨機分配、雙盲、平行分組、安慰劑對照試驗，評估 finerenone 用於患有心臟衰竭 (NYHA II-IV) 及左心室射出分率 $\geq 40\%$ (LVEF $\geq 40\%$) 參與者之發病率和死亡率上的療效與安全性。 A multicenter, randomized, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of finerenone on morbidity and mortality in participants with heart failure (NYHA II-IV) and left ventricular ejection fraction $\geq 40\%$ (LVEF $\geq 40\%$) |
| 4 | 210702 | 【CIRB】110CIRB04076 | 變更案第 6 次 初審 | 林聖皓 Sheng Hao Lin |
| | | | | 一項隨機分組、第三期、開放性試驗，以患有轉移性鱗狀或非鱗狀非小細胞肺癌病人為對象，探討皮下給予 Pembrolizumab 相較於靜脈給予 Pembrolizumab，在併用含鉑類雙重化療作為第一線治療時的藥物動力學與安全性 A Randomized, Phase 3, Open-label Study to Investigate the Pharmacokinetics and Safety of Subcutaneous Pembrolizumab versus Intravenous Pembrolizumab, Administered with Platinum Doublet Chemotherapy, in the First-Line Treatment of Participants with Metastatic Squamous or Nonsquamous Non-Small-Cell Lung Cancer |
| 5 | 211018 | 【CIRB】110CIRB06125 | 變更案第 2 次 初審 | 陳達人 DarRen Chen |
| | | | | 一項全球、ARX788 第 2 期研究、用於對 T-DM1 和/或 T-DXd 和/或含 Tucatinib 療法有抗藥性或難治性之第二型人類上皮生長因子受體(HER2) 陽性轉移性乳癌患者 A Global, Phase 2 Study of ARX788 in HER2-positive Metastatic Breast Cancer Patients Whose Disease is Resistant or Refractory to T-DM1, and/or T-DXd, and/or Tucatinib-containing Regimens |
| 6 | 211018 | 【CIRB】110CIRB06125 | 變更案第 1 次 初審 | 陳達人 DarRen Chen |
| | | | | 一項全球、ARX788 第 2 期研究、用於對 T-DM1 和/或 T-DXd 和/或含 Tucatinib 療法有抗藥性或難治性之第二型人類上皮生長因子受體(HER2) 陽性轉移性乳癌患者 A Global, Phase 2 Study of ARX788 in HER2-positive Metastatic Breast Cancer Patients Whose Disease is Resistant or Refractory to T-DM1, and/or T-DXd, and/or Tucatinib-containing Regimens |
| 7 | 220511 | 【CIRB】111CIRB02025 | 變更案第 1 次 初審 | 陳守棟 SHOU TUNG CHEN |
| | | | | 一項第三期、隨機分配、開放性試驗，評估在接受 PHESGO+TAXANE 類藥物誘導治療後，GIREDESTRANT 併用 PHESGO 相較於 PHESGO，用於先前未經治療的 HER2 陽性、雌激素受體陽性局部晚期或轉移性乳癌病患的療效及安全性 A PHASE III, RANDOMIZED, OPEN-LABEL STUDY EVALUATING THE EFFICACY AND SAFETY OF GIREDESTRANT IN COMBINATION WITH PHESGO VERSUS PHESGO AFTER INDUCTION THERAPY WITH PHESGO+TAXANE IN PATIENTS WITH PREVIOUSLY UNTREATED HER2-POSITIVE, ESTROGEN RECEPTOR-POSITIVE LOCALLY-ADVANCED OR METASTATIC BREAST CANCER |

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| 8 | 220637 | 【CIRB】111CIRB02042 | 變更案第 1 次 初審 | 陳守棟 SHOU TUNG CHEN |
| <p>一項在 HER2 低表現型乳癌患者中評估輔助治療性癌症疫苗 (AST-301、pNGVL3-hICD) 之療效和安全性的第 2 期試驗 (Cornerstone-001)。</p> <p>A Phase 2 Study to Evaluate the Efficacy and Safety of an Adjuvant Therapeutic Cancer Vaccine (AST-301, pNGVL3-hICD) in Patients with HER2 Low Breast Cancer (Cornerstone-001)</p> | | | | |
| 9 | 220713 | 【CIRB】111CIRB05089 | 變更案第 1 次 初審 | 賴冠銘 KuanMing Lai |
| <p>一項評估 Amivantamab 單一療法及併用標準照護化療治療晚期或轉移性大腸直腸癌參與者的開放性第 1b/2 期試驗</p> <p>A Phase 1b/2, Open-Label Study of Amivantamab Monotherapy and in Addition to Standard-of-Care Chemotherapy in Participants with Advanced or Metastatic Colorectal Cancer</p> | | | | |
| 10 | 190815 | 【CIRB】108CIRB04065 | 期中報告第 3 次 初審 | 蘇維文 Wei Wen Su |
| <p>一項採用多重因子設計的第三期、部分雙盲、隨機分配試驗，在以抗 HBV 核苷(酸)療法接受維持治療的 D 型肝炎病毒慢性感染病患中，評估 50 mg Lonafarnib/100 mg Ritonavir BID 搭配或不搭配 180 mcg PEG IFN-alfa-2a 持續 48 週的治療，相較於 PEG IFN-alfa-2a 單一療法與安慰劑治療的療效及安全性 (D-LIVR)</p> <p>A Phase 3, Matrix Design, Partially Double-Blind, Randomized Study of the Efficacy and Safety of 50 mg Lonafarnib/100 mg Ritonavir BID with and without 180 mcg PEG IFN-alfa-2a for 48 Weeks Compared with PEG IFN-alfa-2a Monotherapy and Placebo Treatment in Patients Chronically Infected with Hepatitis Delta Virus Being Maintained on Anti-HBV Nucleos(t)ide Therapy (D-LIVR)</p> | | | | |
| 11 | 201007 | 【CIRB】109CIRB07120 | 期中報告第 2 次 初審 | 邱南英 Nan Ying Chiu |
| <p>一項隨機分配、開放性、評分者盲性、活性對照、國際性、多中心試驗，針對持續接受選擇性血清素回收抑制劑/血清素正腎上腺素回收抑制劑之難治型重度憂鬱症的成人及老年參與者，評估彈性劑量 Esketamine 鼻用噴霧相較於 Quetiapine 持續性藥效錠之療效、安全性和耐受性</p> <p>A Randomized, Open-label, Rater-Blinded, Active-Controlled, International, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Flexibly Dosed Esketamine Nasal Spray Compared With Quetiapine Extended-Release in Adult and Elderly Participants With Treatment-Resistant Major Depressive Disorder Who are Continuing a Selective Serotonin Reuptake Inhibitor/Serotonin-Norepinephrine Reuptake Inhibitor</p> | | | | |
| 12 | 211010 | 【CIRB】110CIRB03048 | 期中報告第 1 次 初審 | 莊智鈞 Chih Chun Chuang |
| <p>一項多中心、開放性的延伸試驗，針對新生血管型老年性黃斑部病變病患評估以植入型儲藥器系統給予 Ranibizumab 的長期安全性與耐受性(PORTAL)</p> <p>A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY AND TOLERABILITY OF THE PORT DELIVERY SYSTEM WITH RANIBIZUMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (PORTAL)</p> | | | | |
| 13 | 200419 | 【CIRB】109CIRB02027 | 暫停第 1 次 初審 | 邱足滿 TsuMan Chiu |

以外用凝膠 VDO (Lidofenac 1.8%) 治療免疫功能健全之唇皰疹病人為對象，一項開放標示、評估者盲性、隨機分派、有效藥物對照之臨床試驗。

An Open-Label, Evaluator-Blind, Randomized, Active Controlled Study of Topical VDO (Lidofenac 1.8% gel) for Treatment of Herpes simplex Labialis in Immunocompetent Patients.