～～～～請妥善分配時間回答～～～～

※ 注意：全部題目均請作答於試卷內之「非選擇題作答區」，請標明題號依序作答。

一、閱讀以下摘要，回答下列兩題。(20%)

Cummings, Steven R. "Clinical Trials Without Clinical Sites." JAMA Internal Medicine 181.5 (2021): 680-684.

Clinical trials conducted at clinical sites are limited to enrolling people who live nearby and are able to attend visits at clinics. Some types of clinical trials can be performed without clinical sites, which enables people to participate regardless of proximity to a clinical site or limitations that make visits difficult. Trials at clinical sites involve face-to-face relationships with in-person collection of informed consent, examinations, data, and specimens. In contrast, without clinical sites, informed consent and data are obtained online, limited examinations can be performed by telemedicine or visiting research nurses, biospecimens can be collected by visiting nurses or local laboratories, and treatments can be sent to homes or administered by nurses in participants' homes. Trials without clinical sites require internet access and must adapt to the lack of face-to-face interactions with study staff, with communication conducted by email, telephone, or video. Many trials cannot be performed entirely without clinical sites because they require examinations, tests, or treatments that must be given at a clinical site. However, some of the methods required for trials without sites, such as online data collection, follow-up visits by telemedicine or research nurses, and delivery of treatments to home, could reduce the need for visits to clinical sites and reduce the burden of participating in a clinical trial.

(1) 依本文，無場域臨床試驗(clinical trials without clinical sites)，如何取得受試者知情同意? (5%)
(A) 申請免除書面簽署
(B) 研究護理師社區訪視
(C) 試驗主持人家訪
(D) 利用紙本郵寄替代
(E) 以上皆非。若選此項，需註明正確為_____

(2) 無場域臨床試驗(trials without clinical sites)難以進行主要障礙是: (5%)
(A) 預算經費的不足
(B) 檢查治療需實體
(C) 語文文化的隔閡
(D) 醫護團隊的抗拒

(3) 若準備執行無場域臨床試驗(trials without clinical sites)，需要準備哪些事務?(10%)

見背面

二、根據以下摘要，請以中文回答下列問題：(20%)

Topic Significance & Study Purpose/Background/Rationale

Clinical research has always been a part of transplantation; however, with breakthroughs in cellular immunotherapy (CI), such as CAR T-cell and T-cell receptor therapy, the number of clinical research trials in this area has rapidly increased. At our center, there are currently 38 open CI trials with 15 more opening in the next few months. These trials are multifaceted and complex requiring intensive coordination, development of workflows, diligent nursing care, and additional education across departments and treatment settings. To safely and efficiently run a trial, a study start up process must be in place.

Methods, Intervention, & Analysis

Nursing leadership including managers, and an education specialist, played an integral role in the interdisciplinary team collaboration required for conducting successful clinical trials. Nursing leadership began attending site initiation visits and implementation meetings to gain insight into each new clinical trial and develop patient and nursing workflows. Nursing leadership also assists the clinical trial coordinators (CTC) with the creation of a "quick reference" protocol summary education sheet that is used to assist with caring for the patient. A bi-weekly clinical trials operational meeting, attended by nursing leadership and CTCs, was initiated to discuss problems or issues with current trials. To address knowledge deficits related to CI and specific clinical trials, existing education materials were updated and additional education was created as needed. The unit-based orientation was also modified to include content on CI and clinical trials.

Findings & Interpretation

Prior to opening, each new clinical trial now undergoes a standardized process to determine appropriate workflows, outline the patient journey, and identify education needs. Nursing is involved in every step of the process, which has positively impacted the safety and efficacy of the trials.

(1) 請描述本摘要中提及的研究背景與重要性。

(2) 簡述本文中提及的研究護理師角色職責。

(3) 本研究最主要的結果與臨床應用為何？

接次頁

三、選擇題(每題五分，共十題，50%)

題組 A: 新冠肺炎爆發後持續影響世界，除改變人們健康與生活，也對臨床研究影響巨大。文字圖表摘自 Xue 等(2020)文章，請閱讀並回答第 1 至第 3 題。

Since COVID-19 emerged in January 2020, it has caused unprecedented disruption of clinical trials and ongoing patient care. Around 1,000 organizations have reported trial disruption, consistent with a reported ~80% decrease in new patients entering trials per site in April 2020 compared with April 2019. Of all active trials in ClinicalTrials.gov, 13% reported increases in trial duration in March–May 2020, compared with 9% over the same period in 2019. To protect patient safety and trial integrity, the pharmaceutical industry made strides to accelerate trial innovations such as digital tools and virtualization, with support from regulatory guidelines. To help understand the recovery from COVID-19 disruption and the implications for the future conduct of clinical trials, we analysed data from ClinicalTrials.gov between January and July 2020 and surveyed 245 clinical trial investigators and study coordinators from around the world in May. Here, we present the results of this analysis and discuss the ongoing challenges for clinical trials, innovations to address them and actions to maximize impact. (Xue, et. el., 2020, Clinical trial recovery from COVID-19 disruption. *Nature Reviews Drug Discovery*, *19*(10), 662-4)

1. 根據上段文字，本篇文章之宗旨在於：
   A. 探討過去之新冠疫情如何影響重創臨床試驗
   B. 檢視藥廠如何加速臨床試驗
   C. 討論疫情下，未來臨床試驗面臨之挑戰
   D. 研究如何提升後疫情時代臨床試驗之數量

2. 關於新冠肺炎疫情之於臨床研究之影響，作者未提到：
   A. 2020 年參與臨床試驗之病人，比過去同期少了八成
   B. 為了確保病人安全及臨床試驗之完整，藥廠提倡加速臨床試驗之進行
   C. 作者實際調查了兩百多位研究者之相關看法
   D. 許多研究機構已回報，疫情期間，臨床試驗大受影響

3. 推測本篇文章之研究法應較接近：
   A. 世代研究(Cohort study)
   B. 隨機試驗(Randomized controlled trial)
   C. 質性研究(Qualitative research)
   D. 橫斷性研究(Cross-sectional)

見背面

承上，同一篇文章，作者 Xue 等人根據其調查結果，繪製成圖一(Fig. 1)及圖二(Fig. 2)，請根據圖一回答第 4 及第 5 題，根據圖二回答第 6 至 8 題。

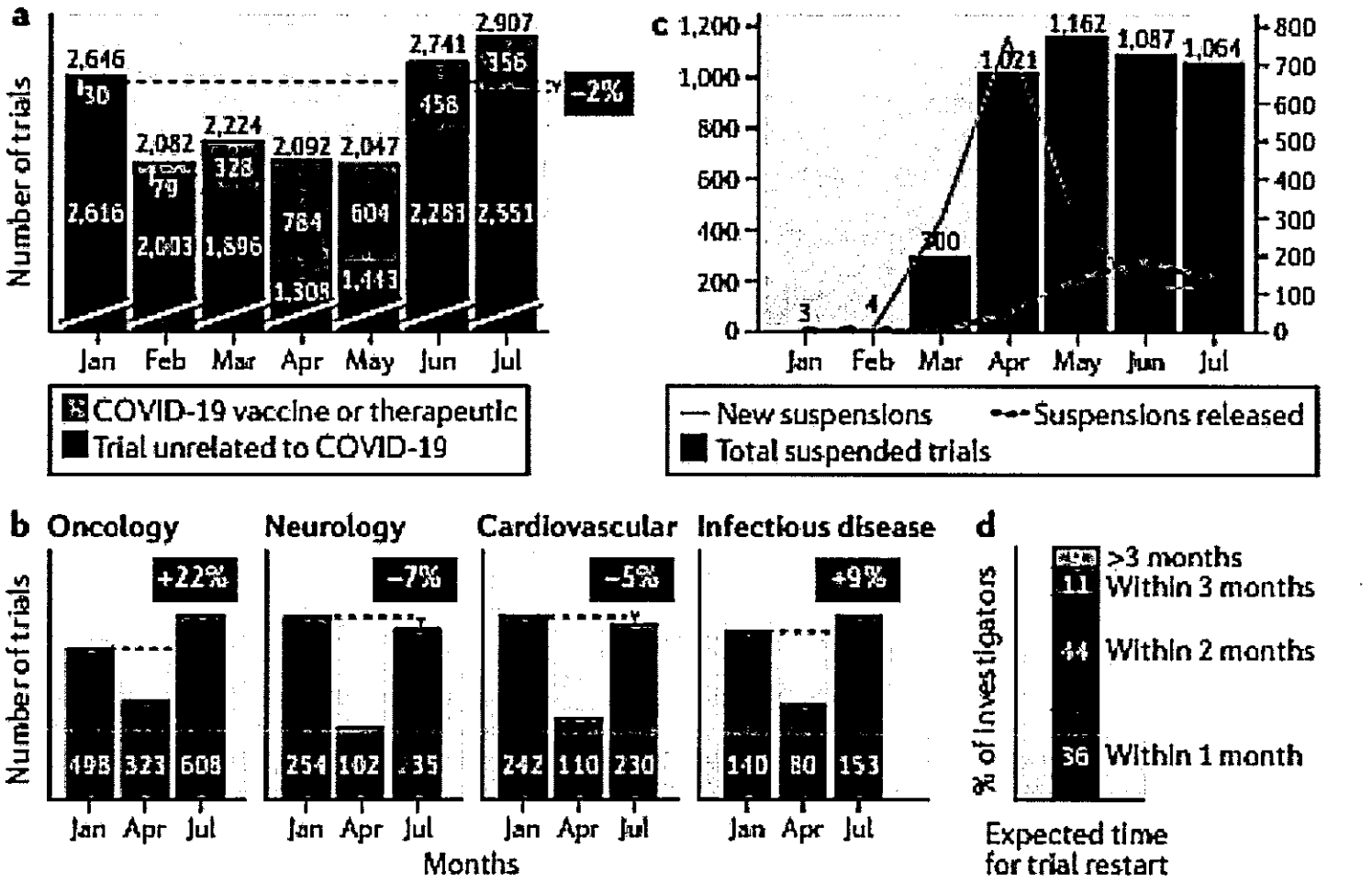

Fig. 1 | **Resumption of global clinical trial activity.** a | New trial starts recorded in ClinicalTrials.gov, including industry, government and investigator-sponsored trials. **b** | New trial starts in four therapeutic areas with the highest trial volume. **c** | Trials suspended in ClinicalTrials.gov explicitly citing COVID-19. **d** | 245 clinical trial investigators were surveyed on expectation of timing to trial restart between 8–18 May 2020. The countries most represented were the US (104), UK (33), Italy (19), Germany (17), Spain (16), France (12).

4. 下列何項為圖一(Fig. 1)主要想展現之資訊?
   A. 後疫情時代全球臨床試驗恢復之狀況
   B. 比較 2019 與 2020 年逐月臨床試驗之數量
   C. 比較疫情前後四大科臨床試驗之數量
   D. 綜觀疫情如何影響臨床試驗之數量

5. 依圖一(Fig. 1)，下列與「新冠肺炎之臨床試驗新案(COVID 新案)」相關之描述，何者最正確?
   A. COVID 新案於四到五月時增幅最大
   B. 七月時之 COVID 新案比同年一月減少了約 2%
   C. 六月後可見因新冠疫情而暫停的研究持續恢復，且恢復趨勢持續成長
   D. 此圖所調查的 COVID 新案多是在美國等地執行

接次頁

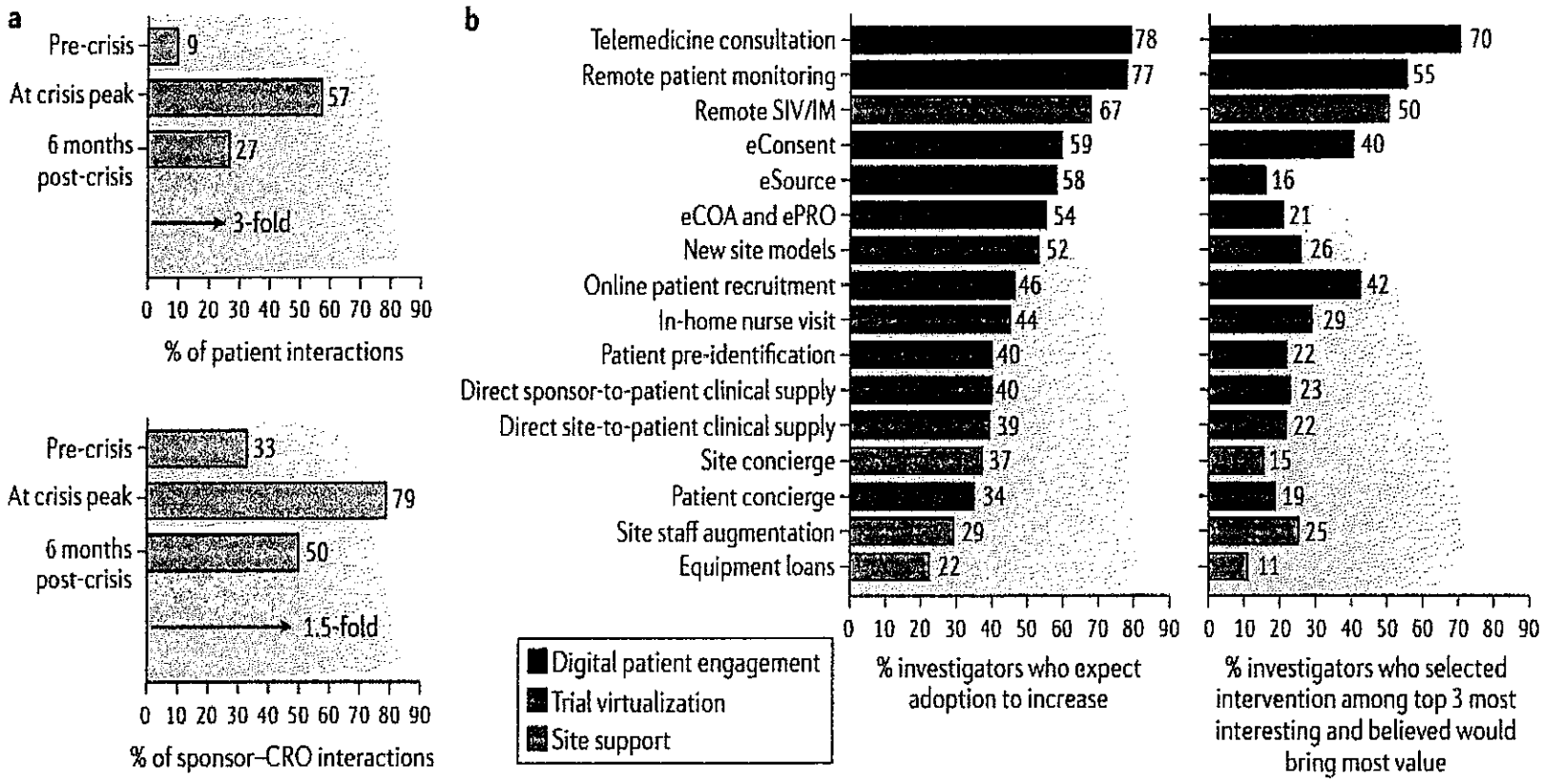

Fig. 2 | **Remote engagement and trial digitization expected to persist post-crisis. a** | A total of 245 clinical trial investigators were surveyed on the percentage of patient and sponsor–contract research organization (CRO) interactions taking place remotely before the crisis and their expectations for crisis peak and the future. **b** | Responses from investigators when asked whether each of 16 trial interventions presented in randomized order would increase in adoption post-crisis, and to select up to three interventions that they were most interested in and believed would bring most value. COA, clinical outcome assessment; IM, investigator meeting; PRO, patient-reported outcome; SIV, site initiation visit.

6. 圖二(Fig. 2)主要想傳達下列哪項訊息?(圖表顏色深淺不影響答題)
   A. 疫情前運用遠距或數位方式進行研究的比例
   B. 以遠距或數位方式進行臨床研究之優缺點
   C. 研究參與者以遠距或數位模式參與研究之接受度
   D. 疫情後持續以遠距或數位策略進行研究之預測

7. 圖二(Fig. 2)註解中敘述了資料來源，應為下列何者?
   A. Clinicaltrails.gov 網站上之資料
   B. 臨床試驗研究者調查
   C. 進行臨床試驗研究之機構
   D. 研究參與者

8. 依圖二(Fig. 2)，若你為研究護理師，你預見未來研究領域可能會有何項改變?
   A. 雖疫情期間，研究傾向運用遠距或數位進行，但疫情後會逐漸回覆用非遠距之傳統研究法
   B. 疫情後可能連研究機構與贊助商之聯繫均會以遠距或數位方式進行
   C. 疫情後能恢復多少臨床試驗的數量仍很難說
   D. 病人對於遠距或數位模式之臨床試驗之接受度將持續提升

見背面

題組 B

請閱讀下列文獻摘要後，回答第 9 及第 10 題。

【註：本摘要發表年代為 20 年前，與現今狀況或有不同，請根據文獻摘要回答，而不是依照目前現況；摘要出處: Raja-Jones, H. (2002). Role boundaries-research nurse or clinical nurse specialist? A literature review. *Journal of Clinical Nursing*, *11*(4), 415-420.】

This paper focuses on issues relating to the role components of clinical nurse specialists and clinical research nurses working in breast cancer care. The paper identified issues relate to the lack of agreement as to the role and definition of clinical nurse specialists. At the same time there has been an increase and emergence of clinical research nurses, both within the national health systems and university departments. The review fails to reveal the relationship between these two specialist groups in terms of role overlap and role boundaries. No evidence was found to suggest how clinical research nurse fits into the concept of specialist nursing. The lack of knowledge in this area substantiates the need for further research to be carried out.

9. 此摘要「最」缺乏下列何項重要訊息?
   A. 研究目的
   B. 研究方法
   C. 研究結果
   D. 討論或建議

10. 下列何項敘述最接近摘要所呈現之內容?
   A. 臨床護理專家(clinical nurse specialist)與研究護理師(clinical research nurse)為兩個壁壘分明的專業
   B. 此研究之主要目的為尋找臨床護理專家及研究護理師之角色共通性
   C. 對於臨床護理專家及研究護理師之角色功能與定義需更多研究釐清
   D. 研究結果顯示，研究護理師可能缺乏專業知識

四、請陳述有關「臨床研究護理師」專業發展之現況、面臨的挑戰及建議的因應策略 (10%)

試題隨卷繳回