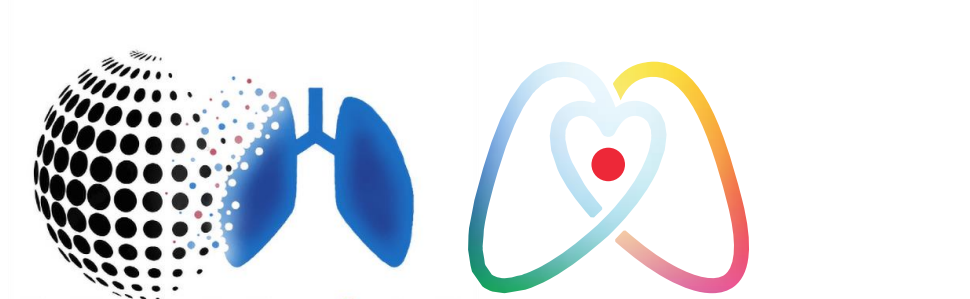


COVID-19臨床試験の実施と今後の課題



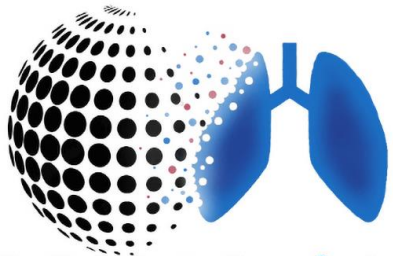
聖マリアンナ医科大学 救急医学 藤谷 茂樹
聖マリアンナ医科大学 横浜市西部病院 齋藤 浩輝
東京大学 大学院医学研究科 医療品質評価学講座 一原 直昭

国際アダプティブ・プラットフォーム試験 REMAP-CAP ご紹介



REMAP-CAP Japan 研究管理委員会
聖マリアンナ医科大学 救急医学 藤谷 茂樹
聖マリアンナ医科大学 横浜市西部病院 齋藤 浩輝
東京大学 大学院医学研究科 医療品質評価学講座 一原 直昭

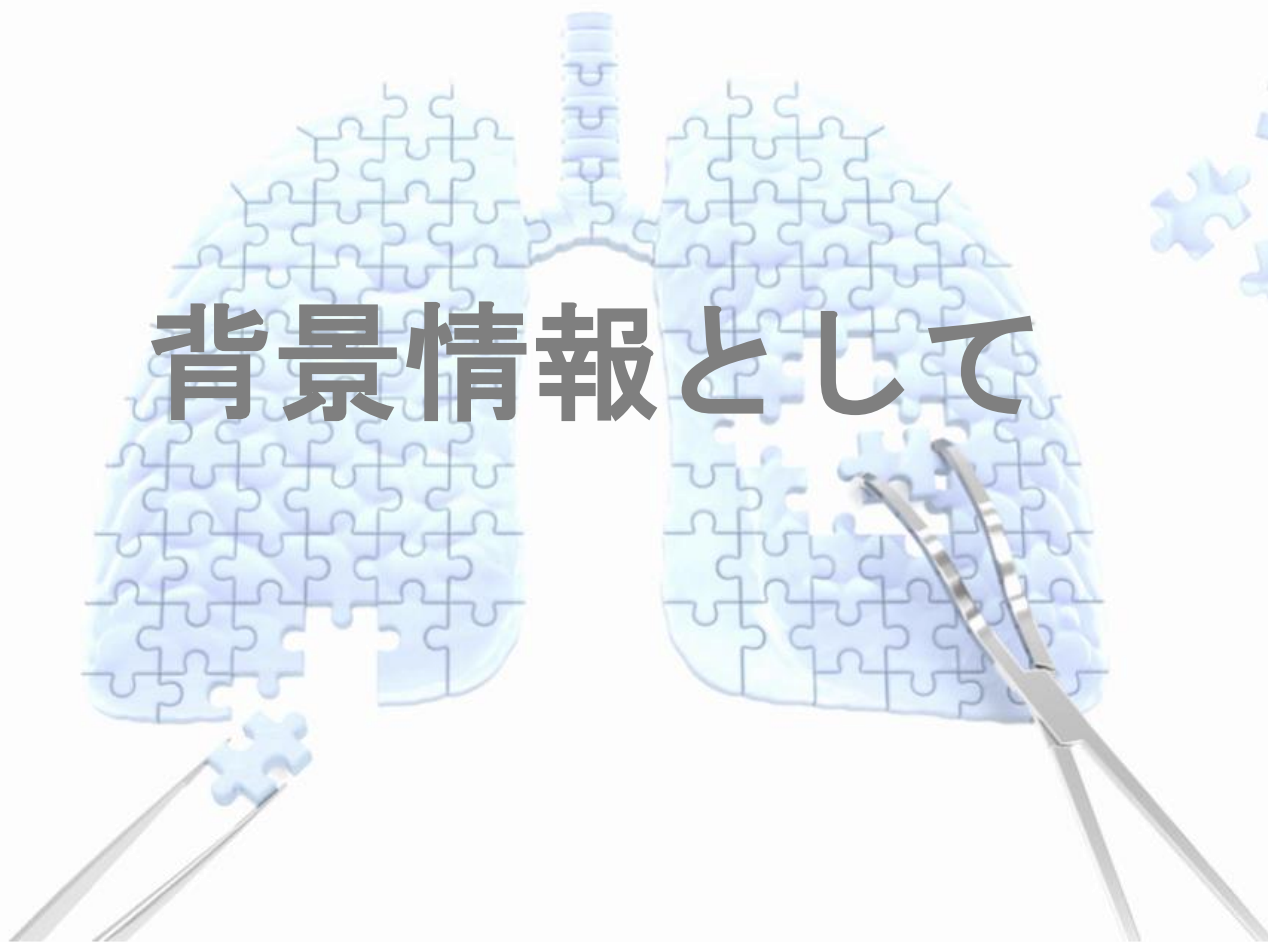
2022年1月13日 製薬協



本日のアジェンダ

- New Normal なClinical Trial
- 平時の臨床試験
- 有事に試験を迅速に走らせるためには
- DCT
- e-Consent
- Embedding

背景情報として



G7加盟国による Clinical Trials Charter “臨床研究大綱”

1. “To avoid the proliferation of trials that do not contribute to valid or actionable scientific evidence, we will prioritise support for randomised controlled trials that address key public health and clinical needs, are well designed and sufficiently sized to generate reliable evidence, are consistent with good clinical practices and ethical principles and engage our citizens to strengthen confidence in science.”

2022年WHO総会で臨床試験に関する議題が採択



World Health
Organization

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY
Agenda item 16.2

A75/A/CONF./9
24 May 2022

**Strengthening clinical trials¹ to provide high-quality
evidence on health interventions and to improve
research quality and coordination**

**Draft resolution proposed by Argentina, Peru,
United Kingdom of Great Britain and Northern Ireland**



Human security and universal health coverage: Japan's vision for the G7 Hiroshima Summit



The COVID-19 pandemic has made an unprecedented impact on the international community and exposed the vulnerabilities of the present global health architecture. Better governance and finance measures are urgently needed to strengthen pandemic prevention, preparedness, and response (PPR) for global health threats and to create more resilient and sustainable health systems that lead to universal health coverage (UHC).

Based on the lessons learned from gaps and vulnerabilities exposed by the COVID-19 pandemic,⁴ the international community needs to further work on policies, governance, and financing to enhance the global health framework with a focus on PPR for health emergencies.

More specifically, an integrated and holistic approach is needed to improve international governance and ensure sustainable financing to rebuild PPR within the global health architecture. This approach requires

- Pandemic Prevention, Preparedness and Response (PPR)の強調
- “100 Days Mission”をもとにR&Dを進める姿勢

非治験ドメイン

抗菌薬（重症市中肺炎）

マクロライド（重症市中肺炎）

人工呼吸器
（重症市中肺炎または重症COVID-19）

抗凝固薬（重症COVID-19）

抗ウイルス薬（インフルエンザ）

免疫調整薬（中等症COVID-19）*

治験ドメイン

COVID-19流行下での課題

<CRC>

- ・進捗状況の確認、注意喚起、新規情報共有をCOVID-19流行下のためメールで実施進捗状況および新規情報共有がメールで実施したためタイムラグが発生
- ・治験薬投与方法の手順見直しと現場情報周知や資料作成
- ・急性疾患のため治験者エントリーのタイミングなど部署間調整
- ・感染対策を講じた状況でのCRCサポートが困難

<薬剤師>

- ・休診日における治験対応や引き継ぎ方法は難易度が高い対応が求められた
- ・視認性の向上と休日当直の盲検薬剤師への対応に配慮が必要
- ・無菌室での調製が必要だったため、ダブルチェック対応に課題が生じた

<事務局>

- ・ステークホルダーがCOVID-19流行で対応に遅延（急性期特有の難しさ）
- ・急速なワクチン開発や普及により臨床試験環境が変化する中で被検者組み入れを継続することとなった

注射薬治験上の課題

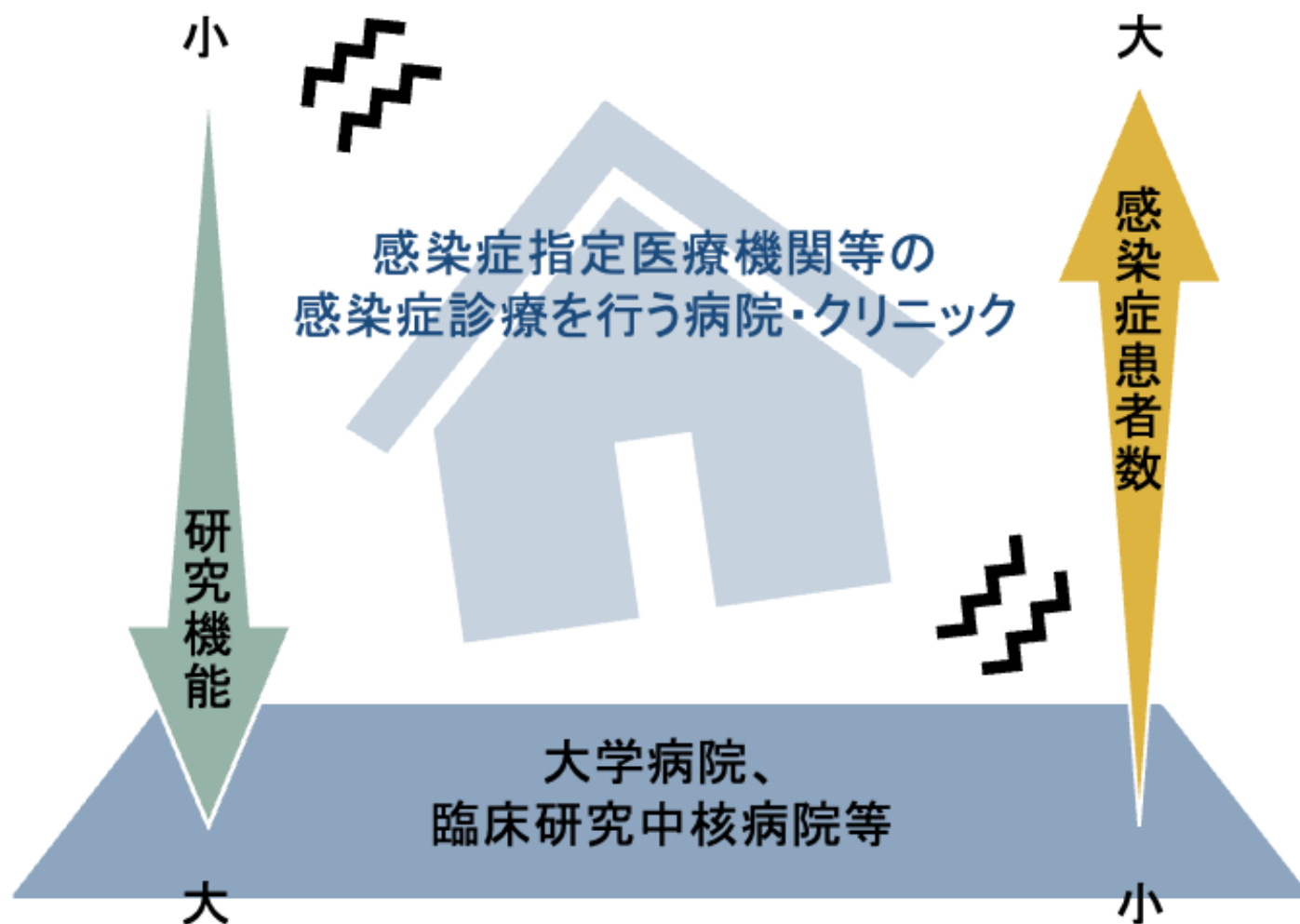
<CRC>

- ・初の注射薬治験のため、CRCと現場スタッフとの共通理解のための意見交換を随時実施

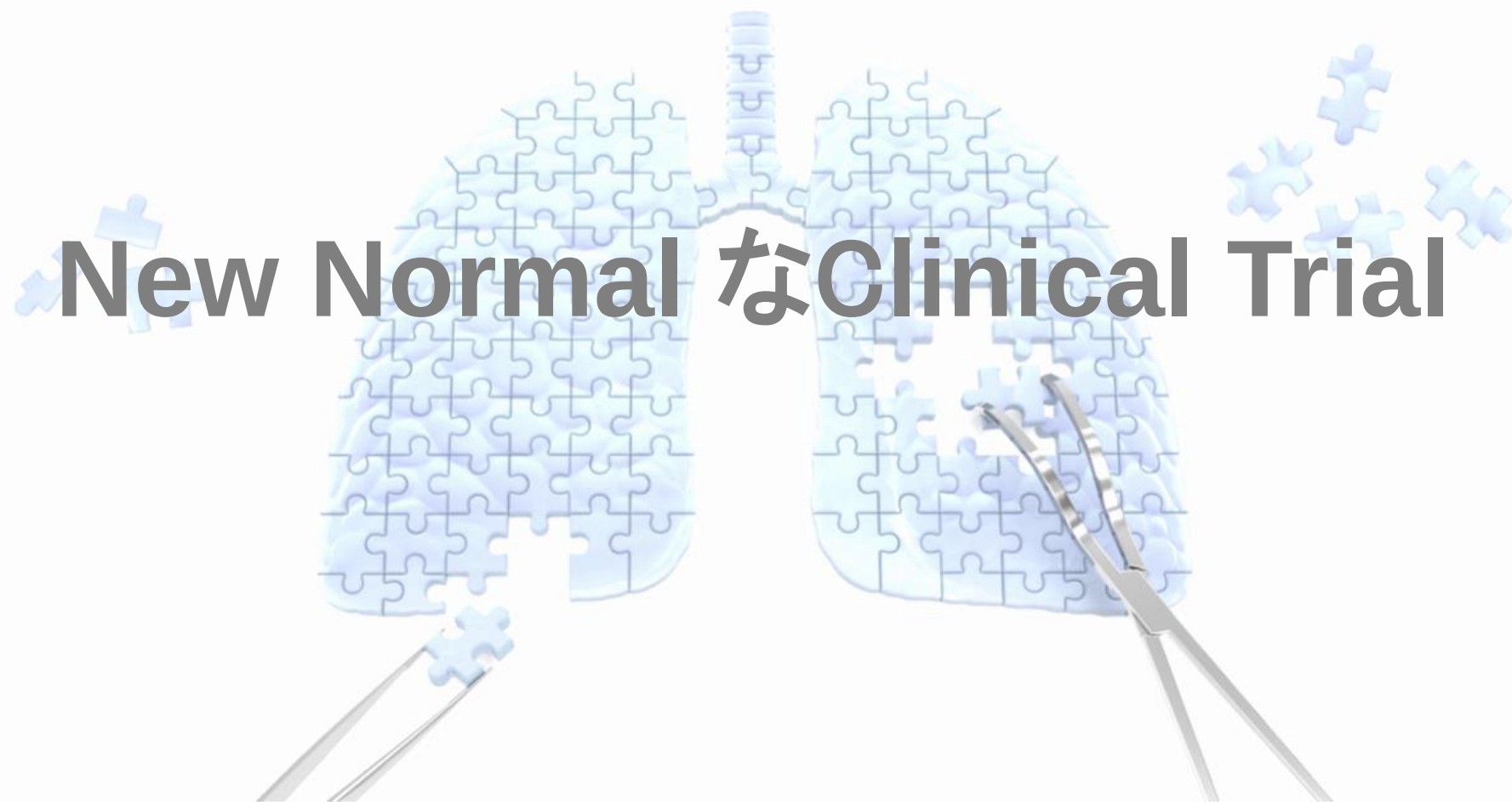
<看護部>

- ・注射薬治験でミスができないというプレッシャーが常にあり、焦りによるインシデントが発生した
- ・治験薬投与やルート漏れ対応などに細かいルールがあるためアクションに制限があった

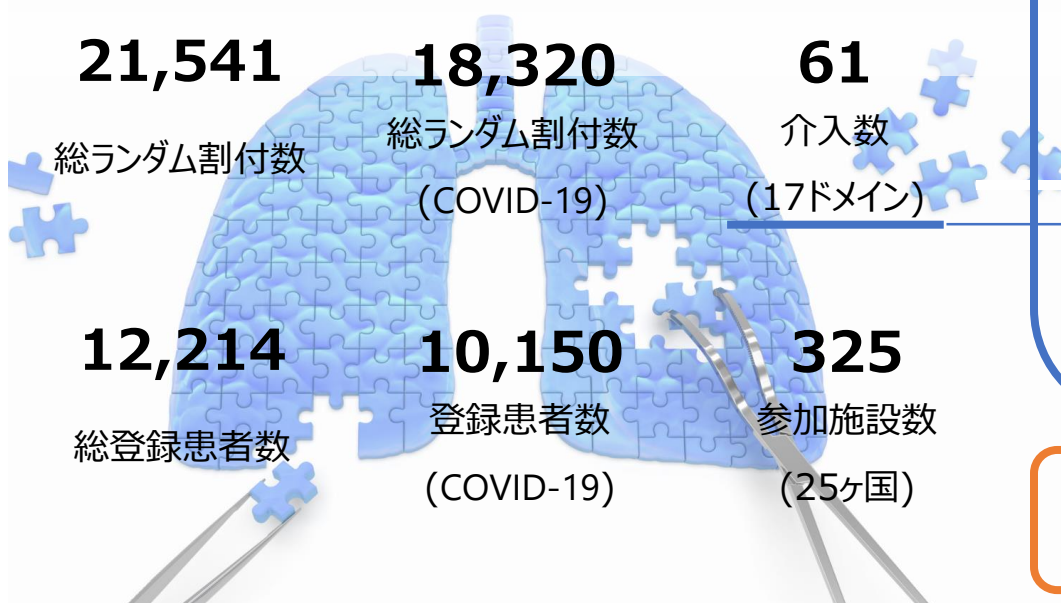
現状の臨床研究実施体制



研究機能を有する医療施設と、
実際に感染症患者が集まる医療施設が分断されている



New Normal な Clinical Trial



非治験ドメイン

抗菌薬 (重症市中肺炎)

マクロライド (重症市中肺炎)

人工呼吸器

(重症市中肺炎または重症COVID-19)

抗凝固薬 (重症COVID-19)

抗ウイルス薬 (インフルエンザ)

免疫調整薬 (中等症COVID-19) *

治験ドメイン

2023年2月16日時点
<https://www.remapcap.org>

* 2022年5月中止

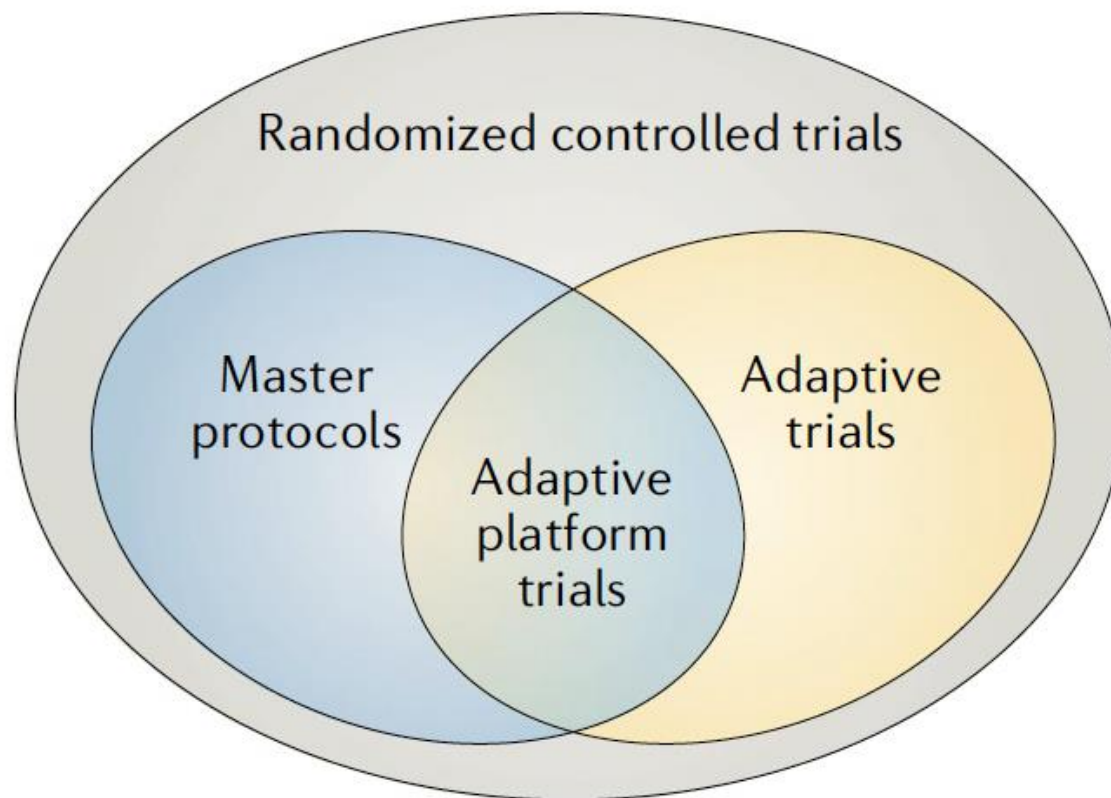
REMAP-CAPの特徴



重症市中肺炎およびCOVID-19を含む新興・再興感染症に対する
臨床試験のプラットフォーム

- **R**andomized (ランダム化)
- **E**mbedding(通常診療への組み込み)
- **M**ultifactorial(同時進行する複数のドメイン)
- **A**daptive(柔軟性)
- **P**latform(パンデミックや新たな臨床疑問に即応可能な基盤)

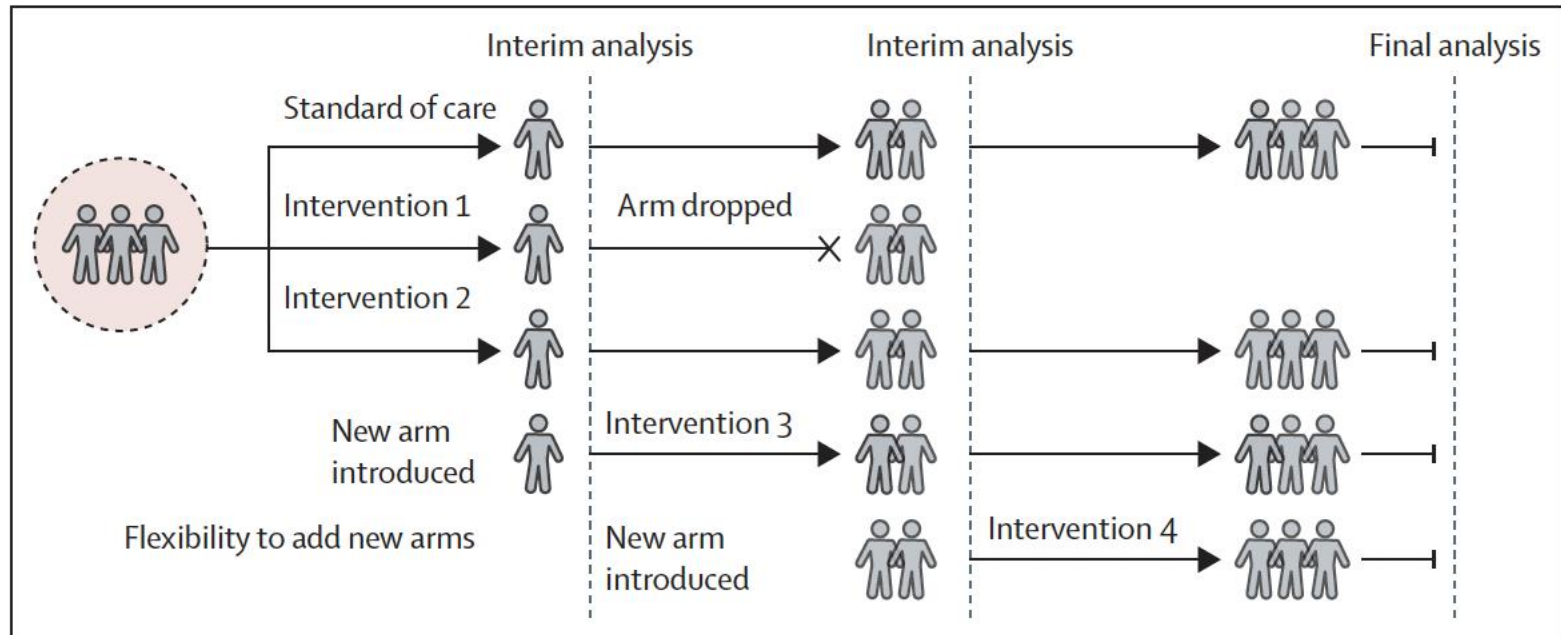
Adaptive Platform Trial (APT)



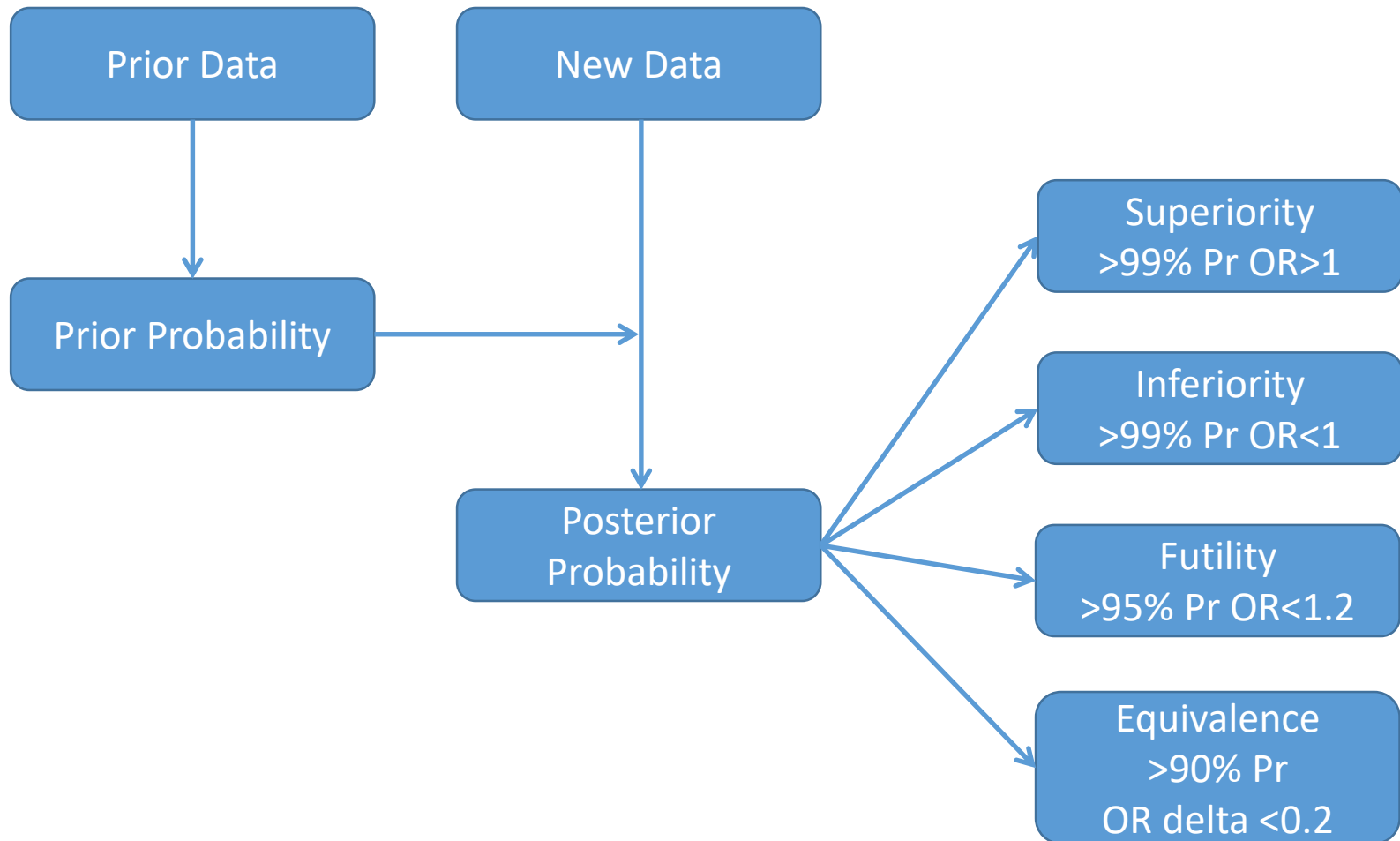
1. APT is a prospective experiment — a trial — of alternative care strategies.
2. a platform, with a master (or core) protocol, upon which multiple questions can be asked about the effectiveness of interventions for a particular disease or condition
3. 'adaptive', distinguishes this class because, it uses information generated during trial conduct to alter subsequent operations in a pre- specified way

Adaptive = “New Normal”?

Platform trial



Adaptive = “New Normal”?

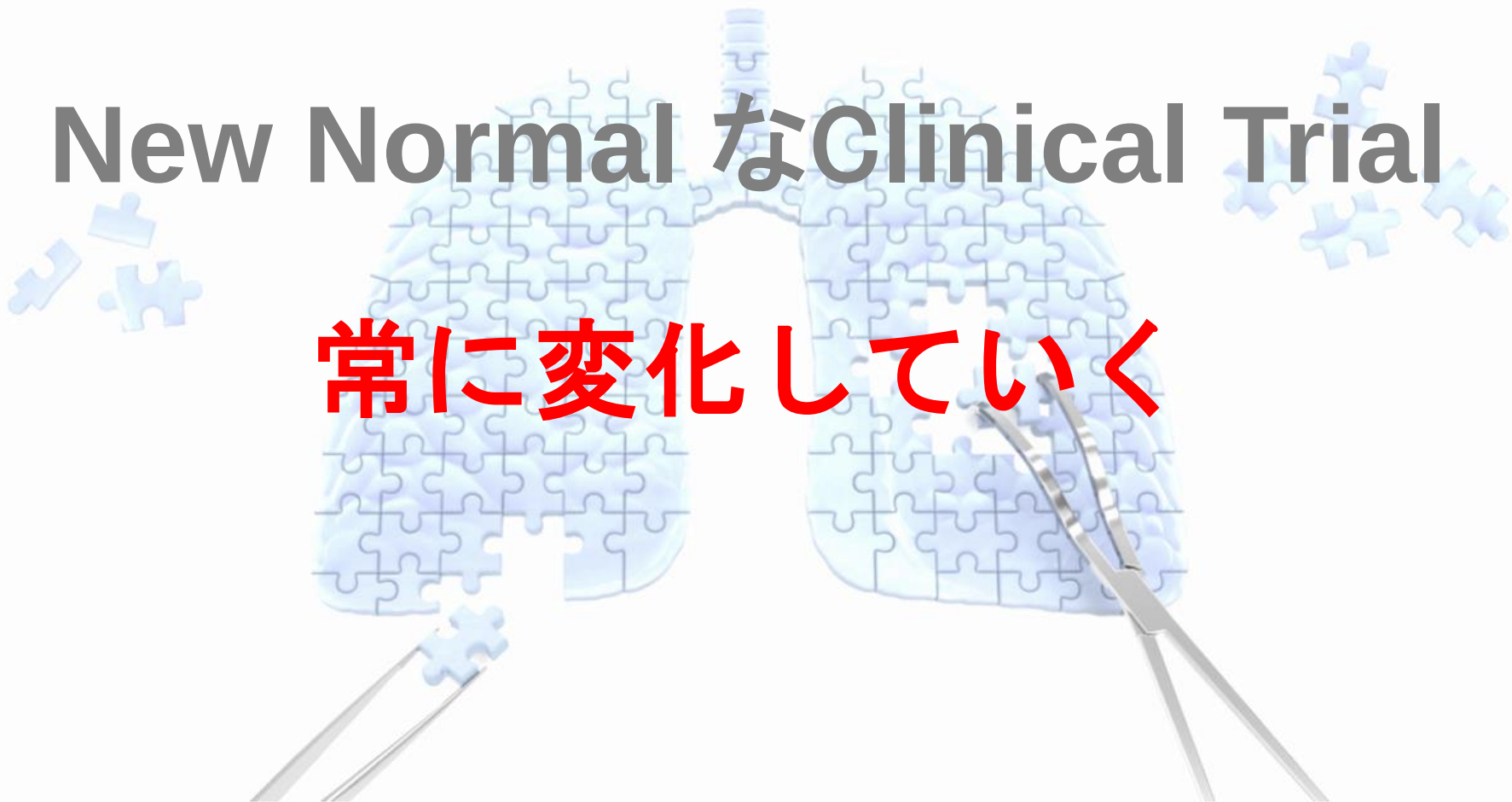


~~重症市中肺炎およびCOVID-19を含む新興・再興感染症~~に対する
臨床試験のプラットフォーム

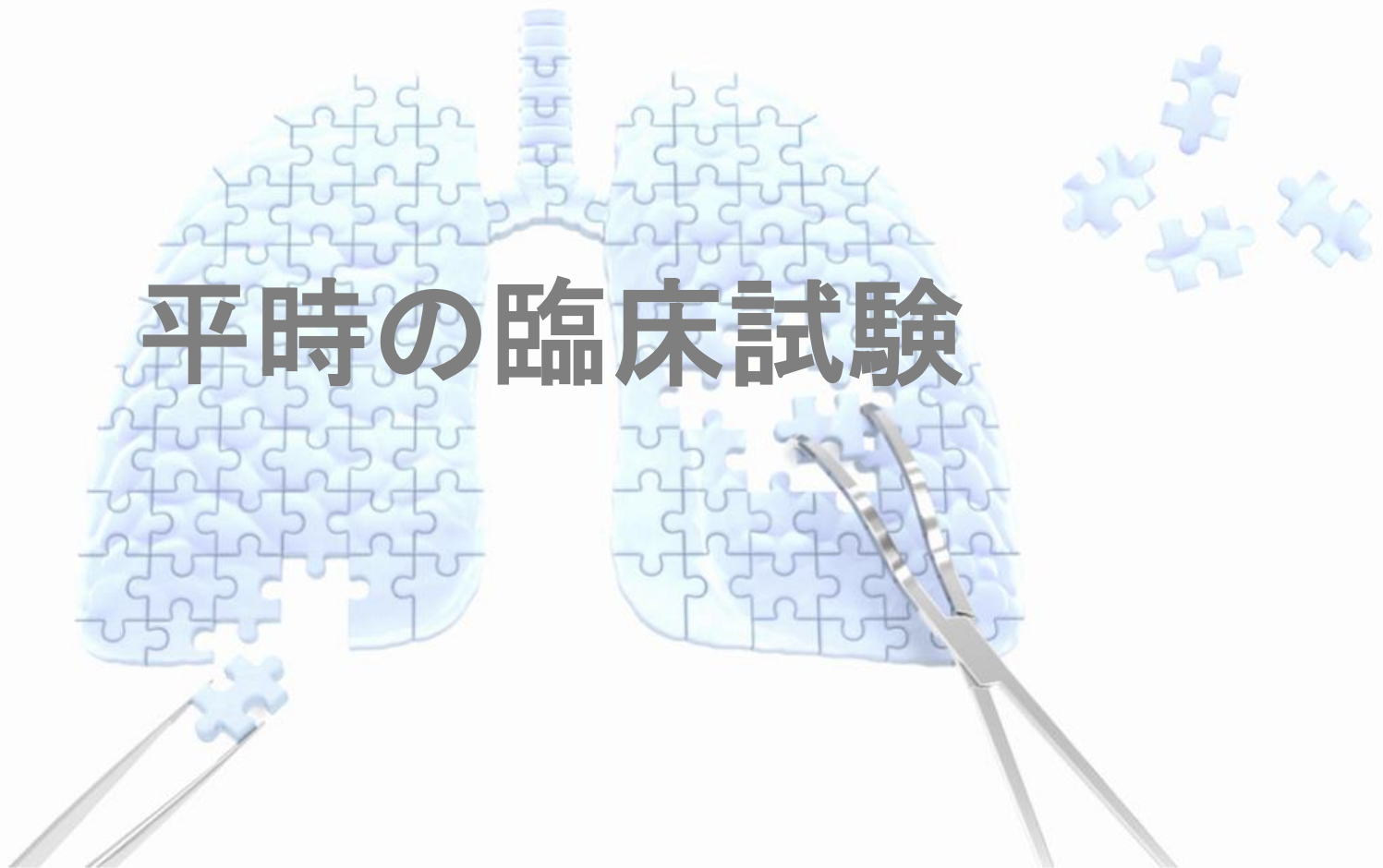
- Randomized (ランダム化)
- Embedding(通常診療への組み込み)
- Multifactorial(同時進行する複数のドメイン)
- Adaptive(柔軟性)
- Platform(パンデミックや新たな臨床疑問に即応可能な基盤)

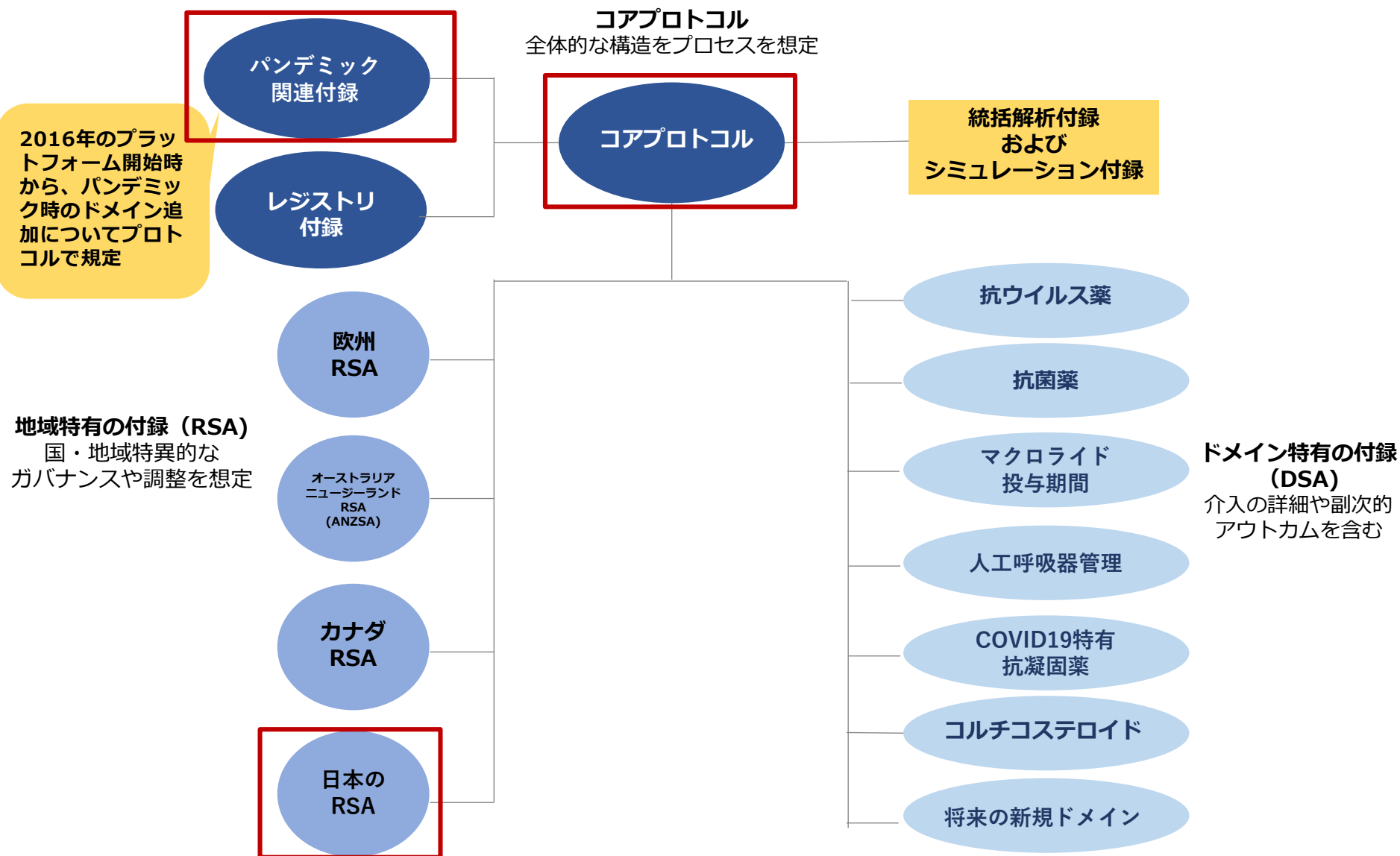
New Normal なClinical Trial

常に変化していく



平時の臨床試験





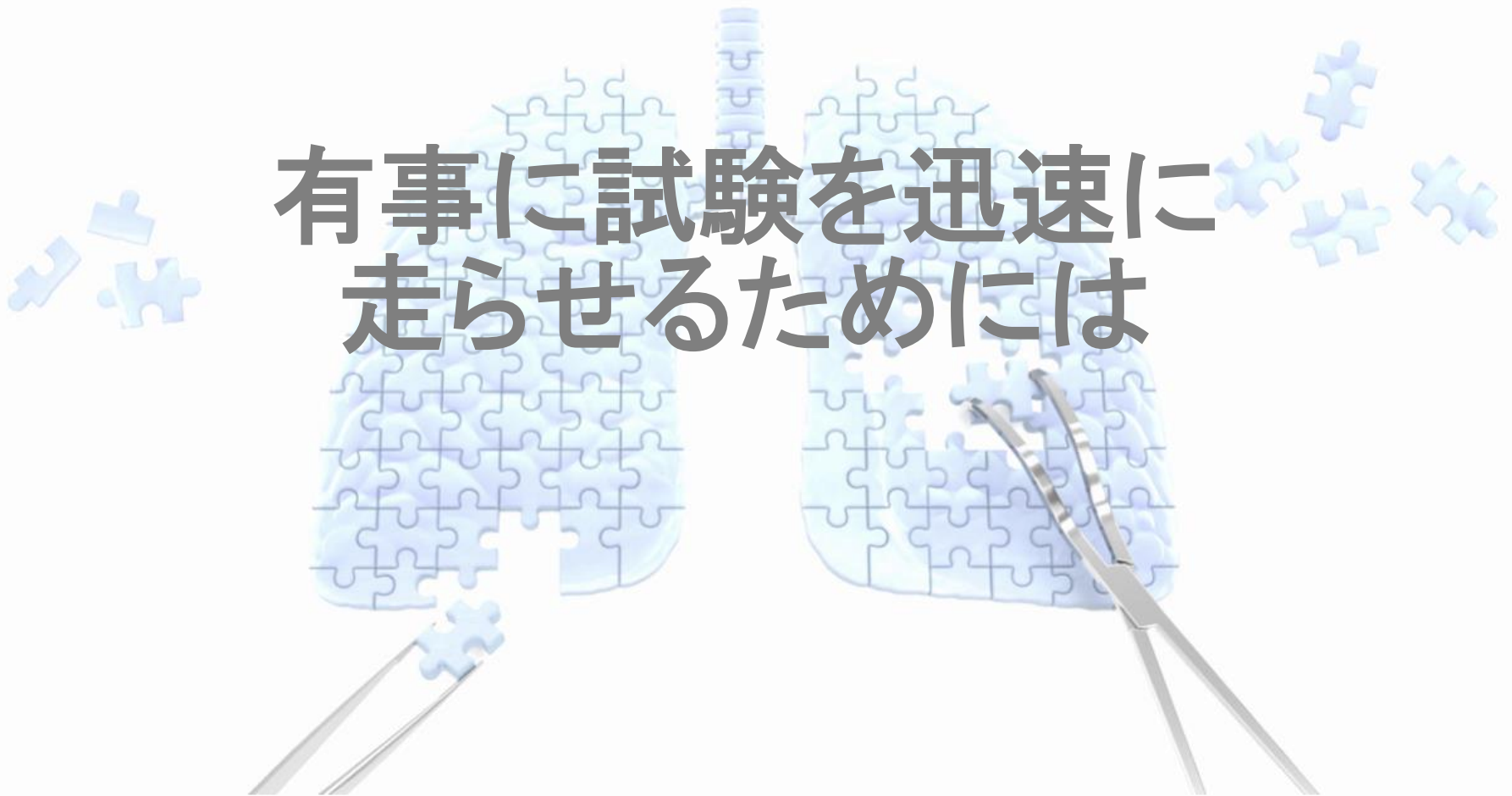
平時から議論を

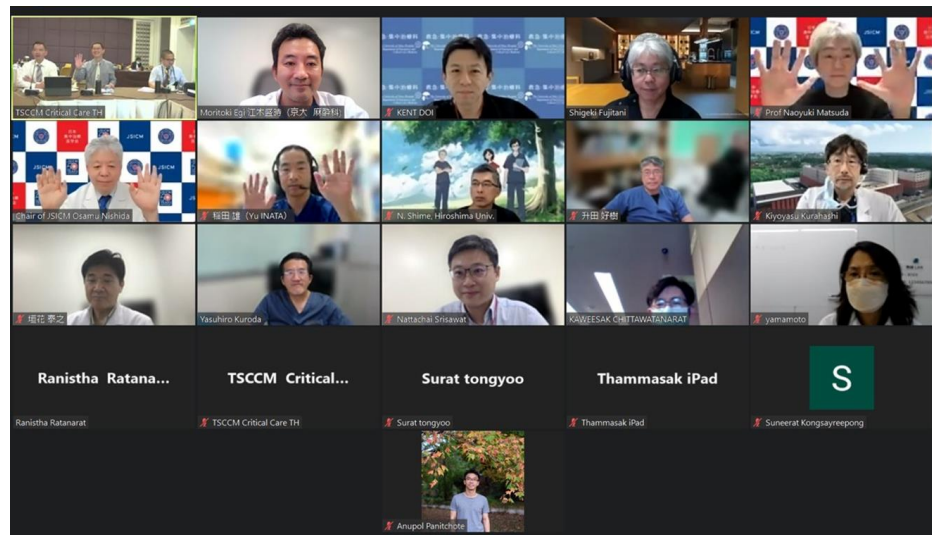
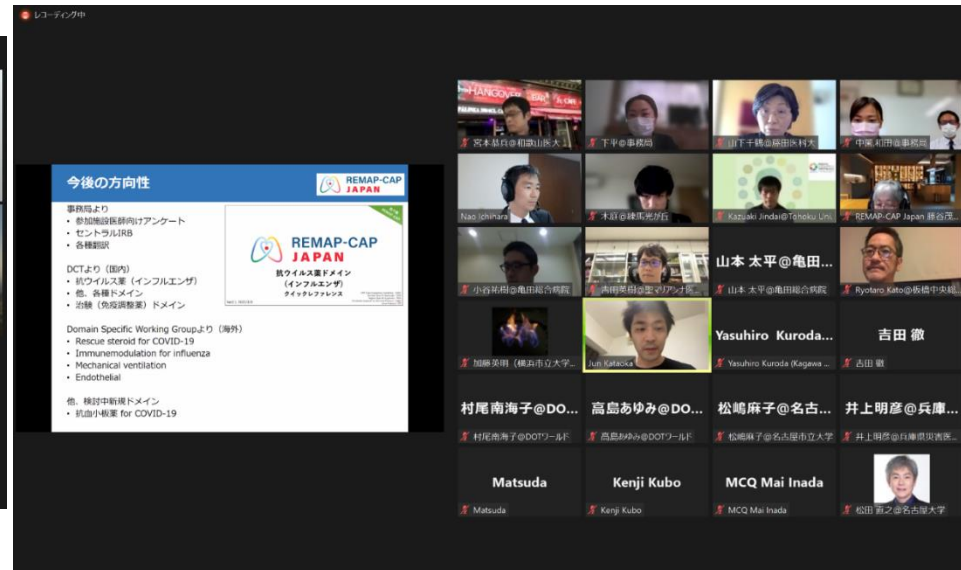
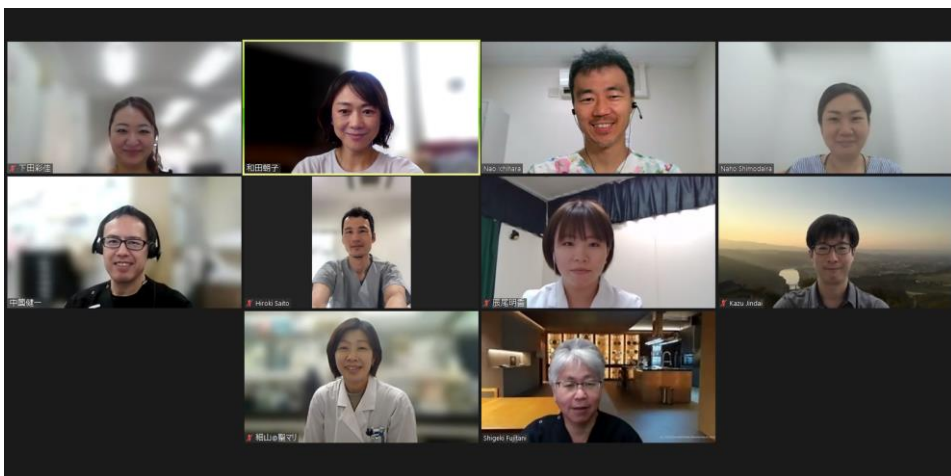
- Conventional <-> Pragmatic
 - Small, strictly defined <-> Large, simple
 - 新規薬 <-> 既存薬
 - Double blind <-> Open label
 - Fixed ratio randomization <-> Response adaptive randomization
 - Non-concurrent control <-> Concurrent control
 - 企業主導 <-> 医師主導
 - 治験 <-> 特定臨床研究
- etc.

参加施設：32 施設



有事に試験を迅速に
走らせるためには





International Trial Steering Committee



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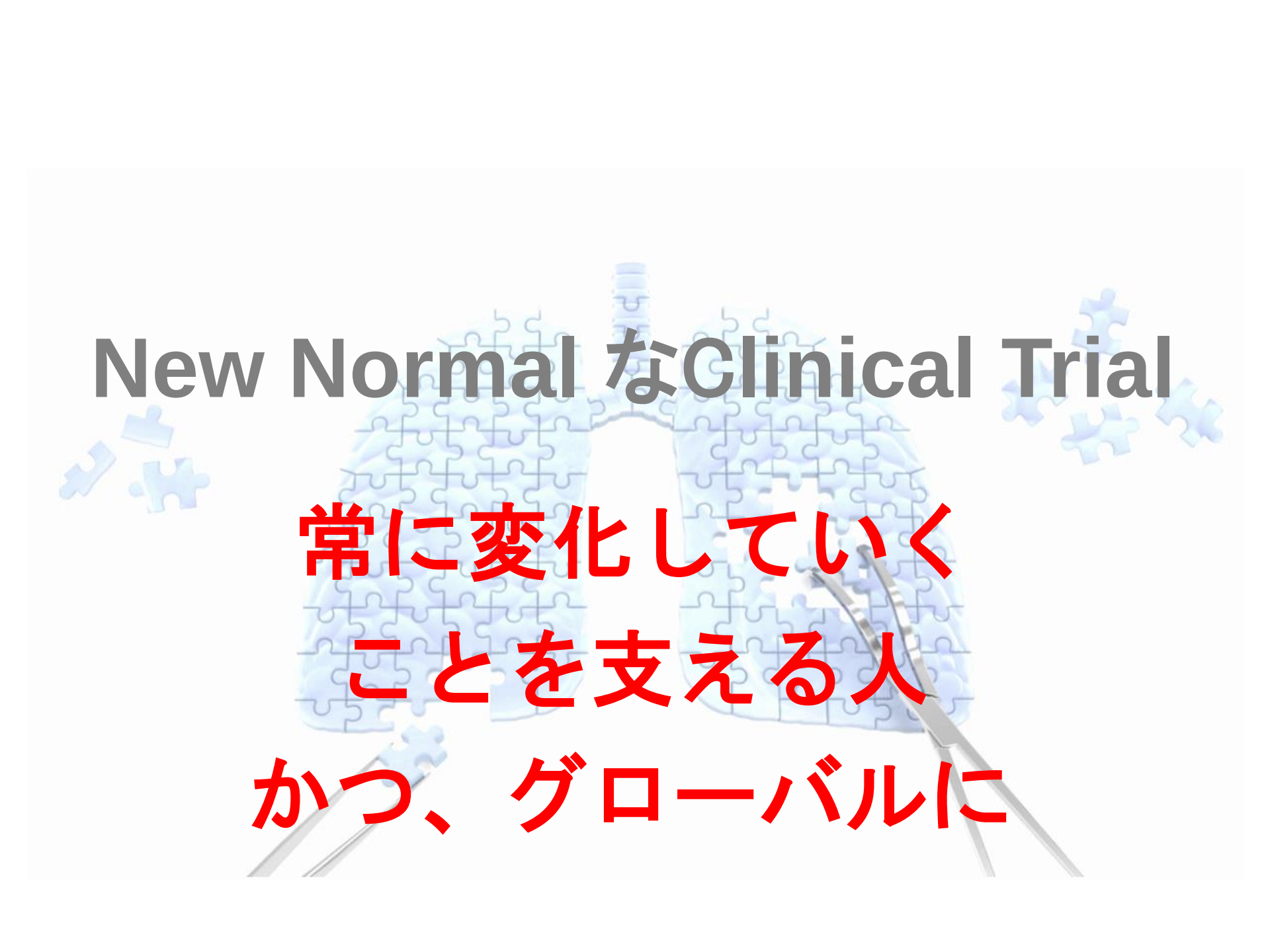


Professor Irene Vella
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Care Physician, Foundation
Director, Executive Director
Australia and New Zealand



Dr Ryan Zepheropoulos
Intensive Care Physician,
Neurologist, Senior
Investigator,
Tutor: @RyanZepheropoulos

New Normal なClinical Trial

The background features a light blue silhouette of a human torso, including the head, neck, and shoulders, composed of interlocking puzzle pieces. Several individual puzzle pieces are scattered around the main figure. At the bottom of the image, a pair of surgical forceps is visible, holding one of the puzzle pieces that form the lower part of the torso.

常に変化していく
ことを支える人
かつ、グローバルに