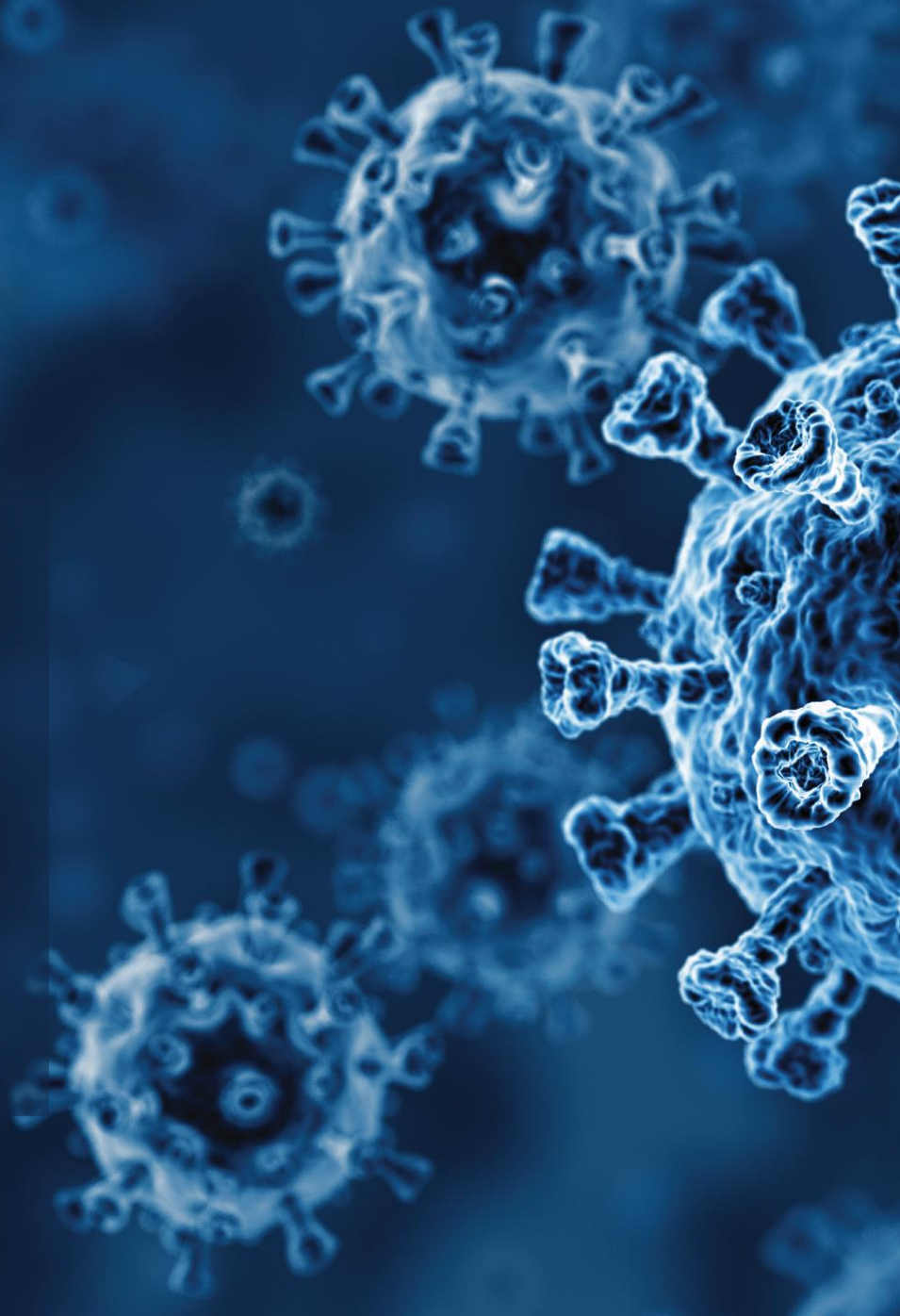
MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Reimagining Clinical Trials: Learning from COVID-19

June 24, 2021



The MRCT Center is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

Brigham and Women's Hospital
Founding Member, Mass General Brigham

HARVARD UNIVERSITY

The MRCT Center

Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

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Reimaging Clinical Trials: Learnings from COVID-19

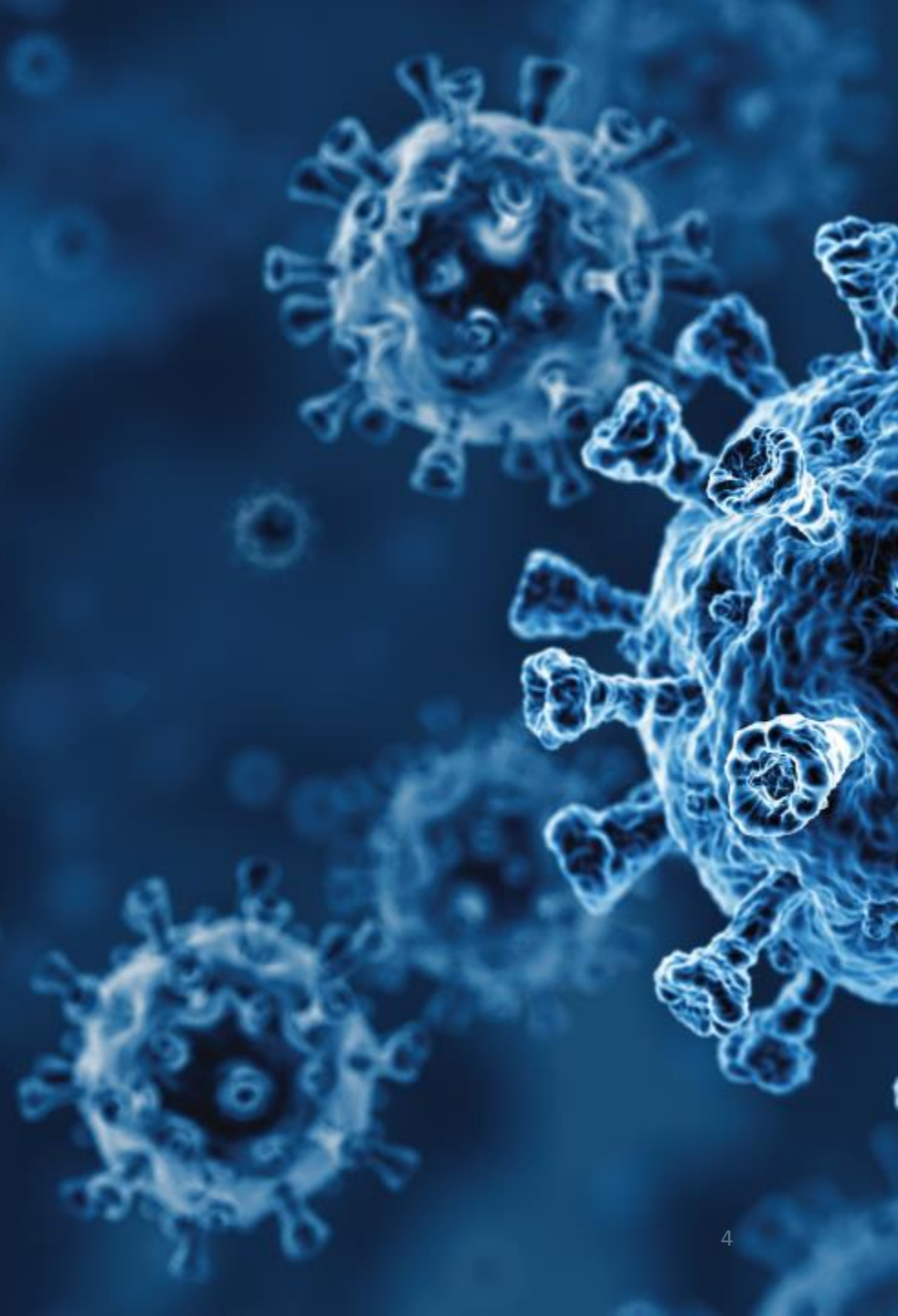
2 Meeting Dates

June 16, 2021, 10AM-1PM EDT

Permissible flexibilities to study conduct and coordination and the implications for the clinical trial workforce in this new environment.

June 24, 2021, 10AM-1PM EDT

Regulatory flexibilities, international cooperativity, and governance.



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Reimaging Clinical Trials: Learnings from COVID-19

Our Goal

- What is the vision for new ways of conducting clinical trials?
- What worked, what did not work, and what we need to analyze further?
- How do we build upon experiences of clinical trials during the COVID-19 pandemic

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June 16, 10:00 AM – 1:00 PM EDT

TIME	TOPIC	SPEAKERS
10:00 AM – 10:30 AM EDT	**Introduction & Keynote speaker:** The Future of Clinical Trials	•**Barbara Bierer**, Faculty Director, MRCT Center •**Sarah White**, Executive Director, MRCT Center •**Esther Krofah**, Executive Director, FasterCures
10:30 AM – 11:30 AM EDT	**First Panel:** Useful and permissible flexibilities: A discussion of regulatory, protocol, and study conduct flexibilities that can and should be sustained in the future, that should be eliminated, and for which further experience is necessary	•**Lindsey Baden**, Division's Director of Clinical Research, Brigham and Women's Hospital/ Dana-Farber Cancer Institute •**Penny Carlson**, Vice President, Head of Global Development Support, Takeda •**Valen Keefer**, Patient Advocate for polycystic kidney disease (PKD) and Organ Donation •**Isaac R. Rodriguez-Chavez**, Head, Global Center of Excellence Strategy for Decentralized Clinical Trials, PRAHealthSciences **Moderator:** •**Paul Kluetz**, Deputy Director, Oncology Center of Excellence, U.S. FDA
11:30 AM – 11:40 AM	**BREAK**	
11:40 AM – 12:40 PM EDT	**Second Panel:** Implications for and need to re-imagine the workforce in a reimagined clinical research enterprise	•**Nicholas Brooke**, Founder & Executive Director of The Synergist, Chief Executive Officer of Patient Focused Medicines Development (PFMD) •**Andrea Ferris**, President and Chief Executive Officer, LUNGEvity •**Andrew (Andy) Lee**, Senior Vice President, Head of Global Clinical Trial Operations, Merck •**Harpreet Singh**, Director of Division of Oncology, U.S. FDA **Moderator:** •**Craig Lipset**, Co-Chair of Decentralized Trials & Research Alliance
12:40 PM – 1:00 PM EDT	**Discussion and wrap-up**	•**Moderators Paul Kluetz** and **Craig Lipset** •**Barbara Bierer,** Faculty Director, MRCT Center •**Sarah White**, Executive Director, MRCT Center

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June 24, 10:00 AM – 1:00 PM EDT

TIME	TOPIC	SPEAKERS
10:00 AM - 10:45 AM EDT	**Introduction & Keynote speakers** *Reimagining Clinical Trials: Learning from COVID-19* – Fergus Sweeney *Aligning global clinical trial requirements* – Ginny Beakes-Read	•**Sarah White**, Executive Director, MRCT Center •**Fergus Sweeney**, Head, Clinical Studies and Manufacturing Taskforce, European Medicines Agency (EMA) •**Ginny Beakes-Read**, Executive Director, Global Regulatory and R&D Policy, Amgen
10:45 AM - 11:40 AM EDT	**First Panel –** Enabling regulatory flexibilities in a global context	•**Taras Carpiac**, Executive Director, Innovation & Process Improvement, Amgen •**Lauren Hartsmith,** Director of Regulatory Affairs, Advarra •**Richard Moscicki**, Chief Medical Officer and Executive Vice President of Science and Regulatory Advocacy, PhRMA •**Névine Zariffa**, Principal and Founder, NMD Group **Moderator:** •**Barbara Bierer**, Faculty Director, MRCT Center
11:40 AM – 11:50 AM	**BREAK**	
11:50 AM - 12:45 PM EDT	**Second Panel** – Regulatory cooperation and communication and issues of governance in a global pandemic	•**M. Khair ElZarrad**, Deputy Director, Office of Medical Policy at Center for Drug Evaluation and Research (CDER), U.S. FDA •**Owen Fields**, Vice President for Regulatory Strategy, Research and Development, Pfizer •**Steven Kern**, Deputy Director of Quantitative Sciences, Bill and Melinda Gates Foundation •**Fergus Sweeney**, Head, Clinical Studies and Manufacturing Taskforce, European Medicines Agency (EMA) **Moderator:** •**Mark Barnes**, Faculty Co-Director, MRCT Center; Partner, Ropes & Gray
12:45 PM – 1:00 PM EDT	**Discussion and wrap-up**	•**Barbara Bierer**, Faculty Director, MRCT Center •**Mark Barnes**, Faculty Co-Director, MRCT Center; Partner, Ropes & Gray

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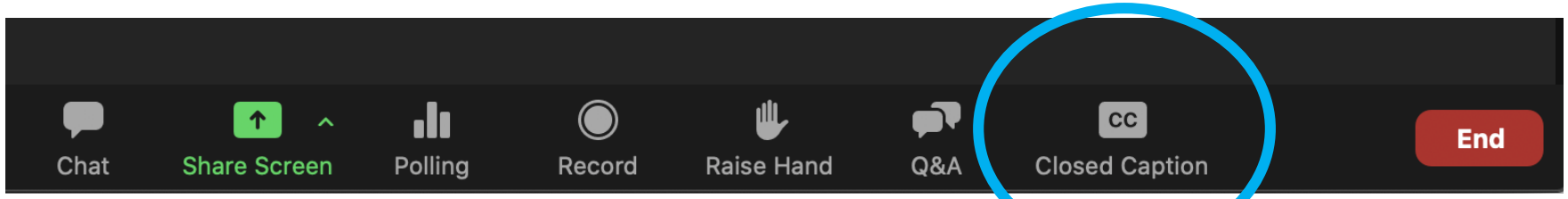
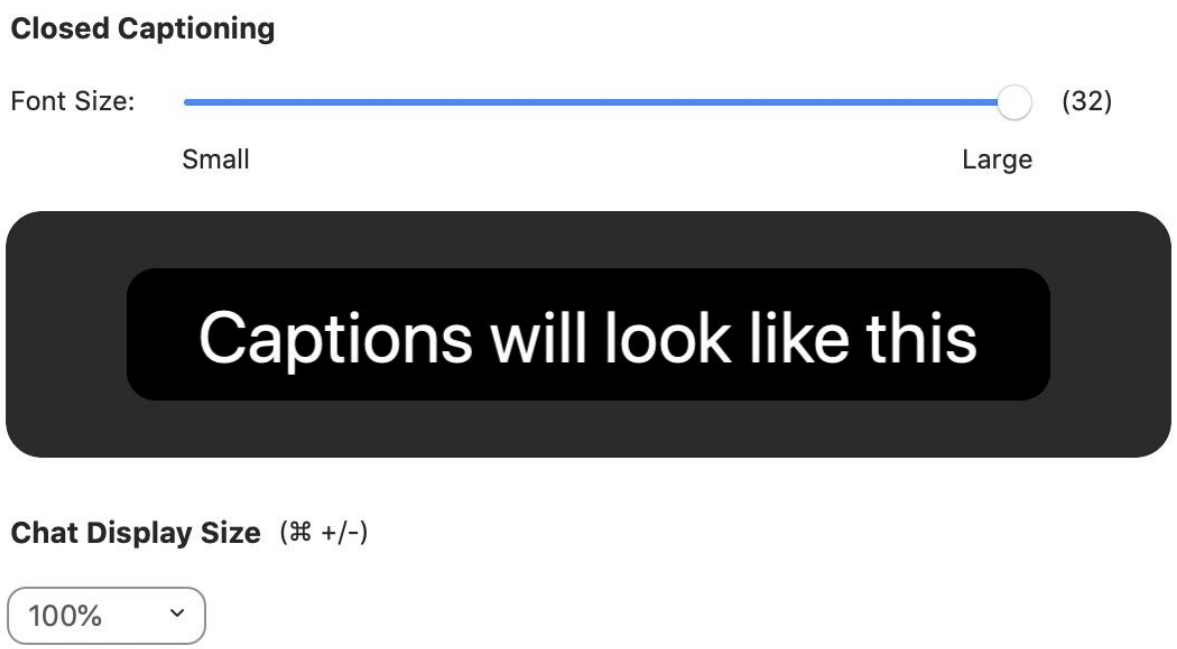
Closed Caption Settings





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Thank you to the Planning Committee

Maria Apostolaros, PhRMA

Ginny Beakes-Read, Amgen

David Peloquin, Ropes & Gray

Michele Russell-Einhorn, Advarra

Shona Sanchita Pendse, Kowa

Jessica Scott, Takeda

Moke Sharma, Alexion

Michael Steel, Novartis

Fergus Sweeney, EMA

<u>MRCT Center team</u>

Carmen Aldinger

Barbara Bierer

Sarah White

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Keynote 1: Reimagining Clinical Trials: Learning from COVID-19

Fergus Sweeney,

Head, Clinical Studies and Manufacturing Taskforce, European Medicines Agency (EMA)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reimagining Clinical Trials: Learning from COVID-19

Presented by Fergus Sweeney on 24 June 2021
Head, Clinical Studies and Manufacturing Task Force, European Medicines Agency

An agency of the European Union

Disclaimer

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The presenter does not have any conflict of interests.

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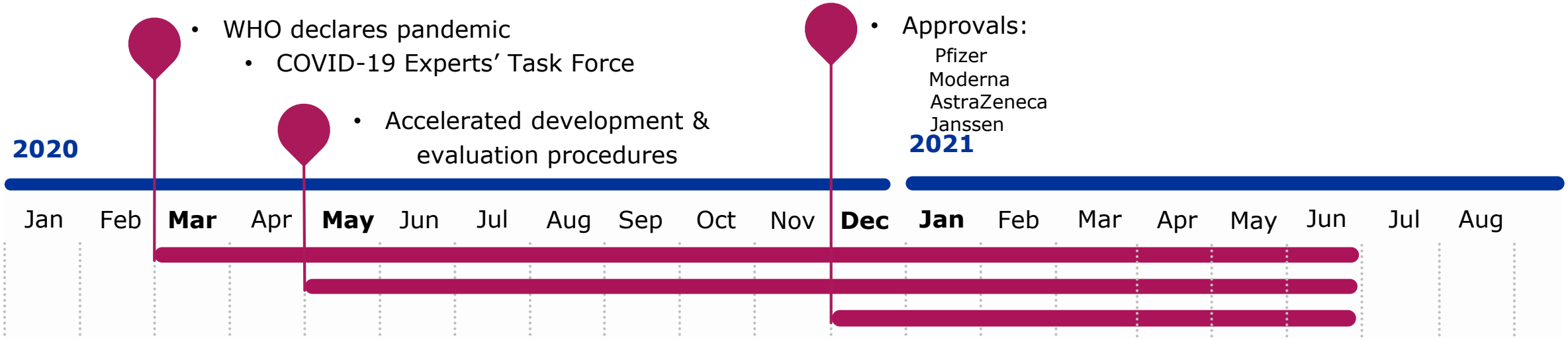
Milestones in EMA response to COVID-19 pandemic



Scientific & regulatory mobilisation

- COVID-19 Task Force
  - EU Network
  - International

Development & evaluation

- Guidance to developers
- Early scientific advice
- Rapid procedures

Essential medicines' supplies

- EU coordination
- Preventing shortages

Transparency & outreach

- Public engagement
- Communication

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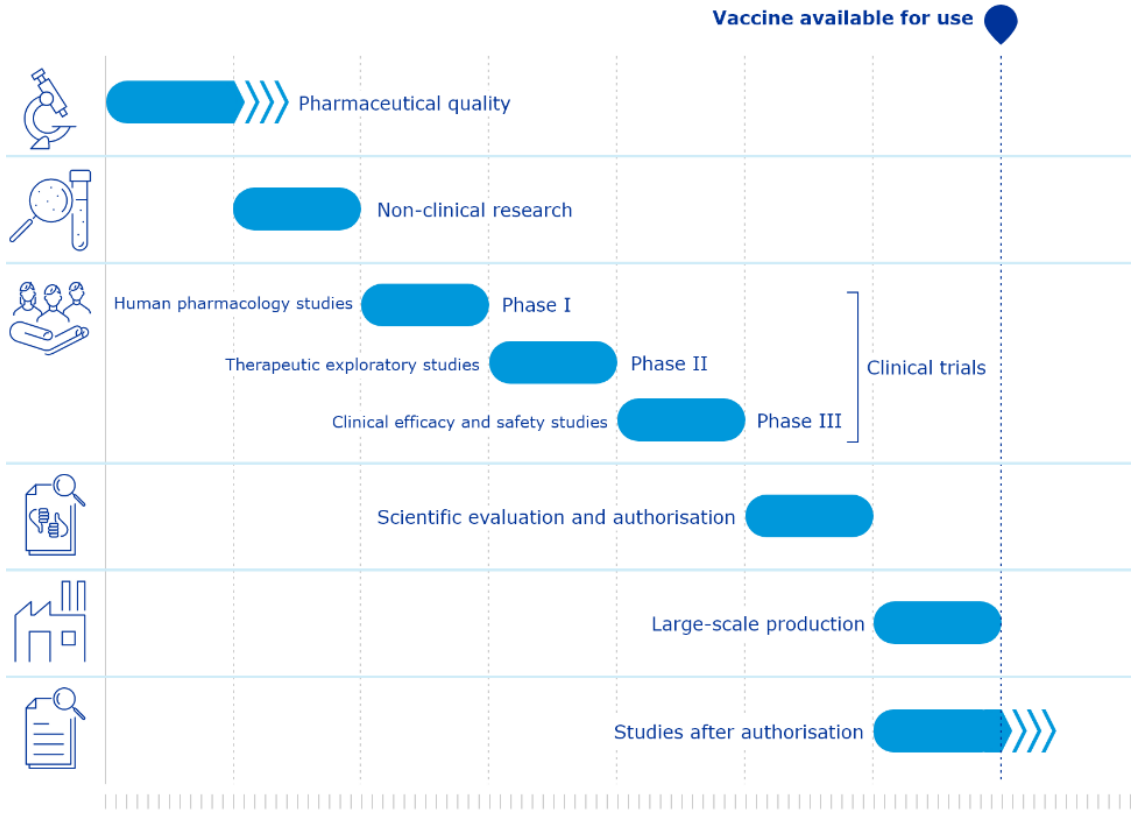
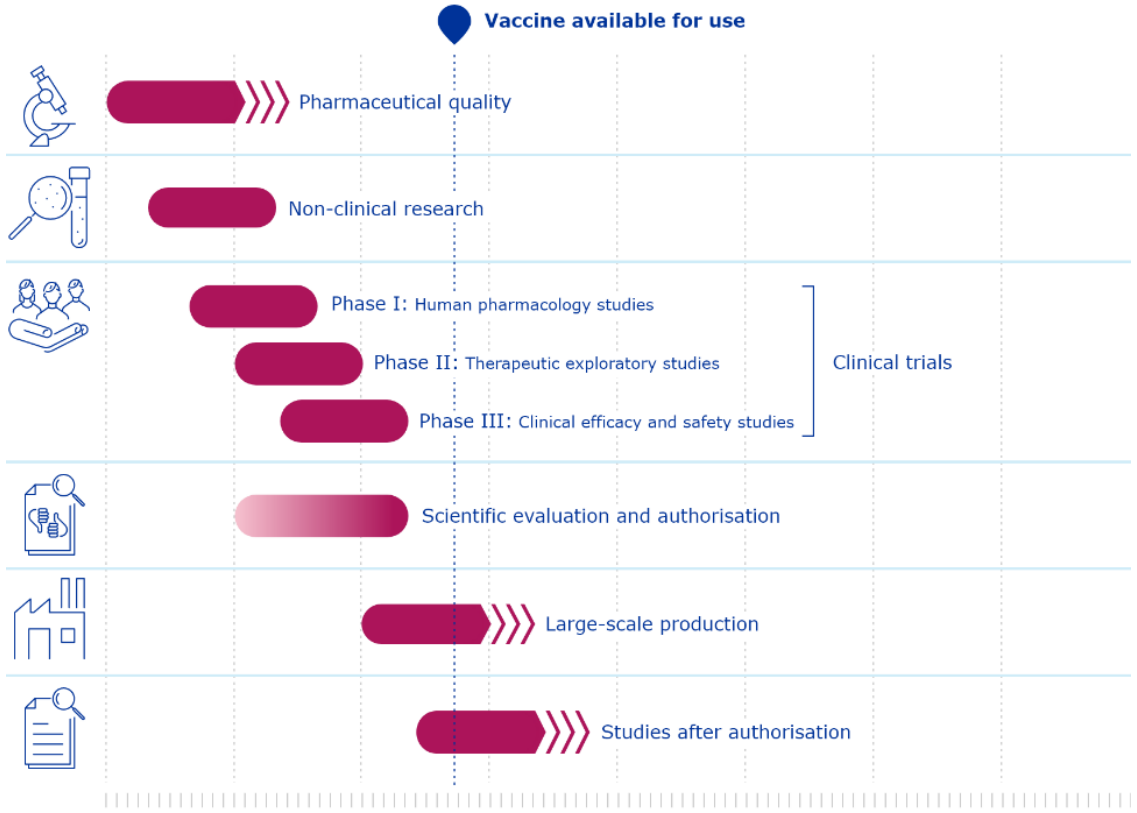
COVID-19 vaccines compared with standard vaccines



Standard Vaccines



COVID-19 Vaccines

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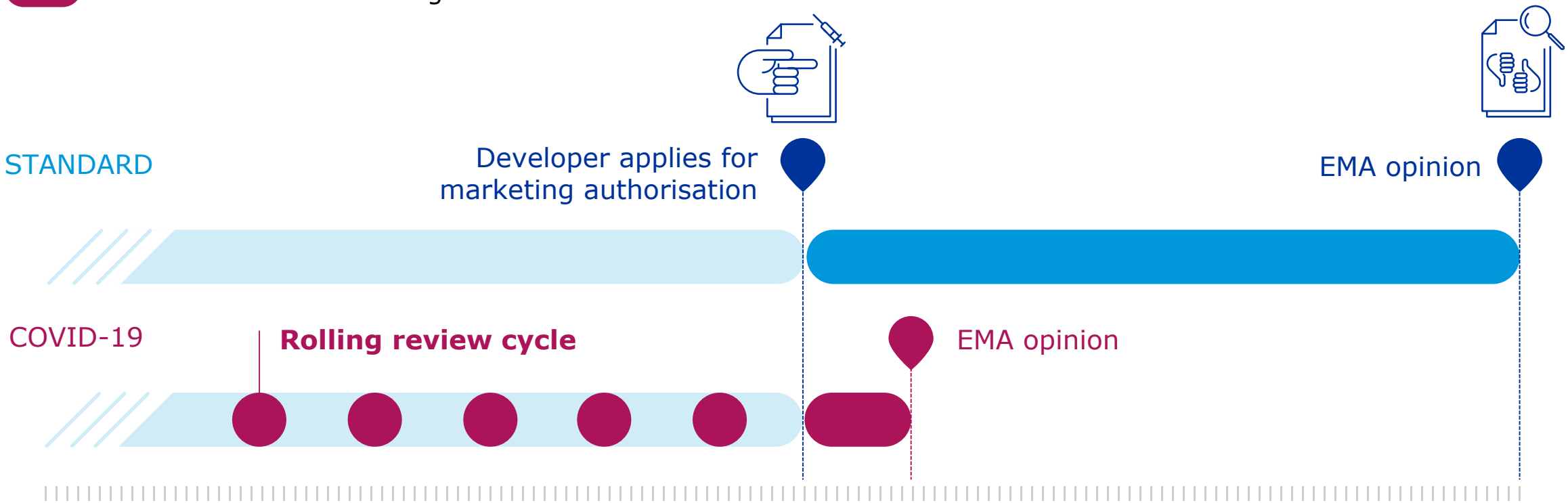
Rolling review and Marketing Authorisation

Research & development

Standard EMA evaluation

EMA evaluation with rolling review



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Conditional Marketing Authorisation

- Approval for medicines to be used in **public health emergencies**
  - as soon as data available show that benefits outweigh the risks
  - **other data** must be provided by the company, **after approval** (e.g. long term protection data)

- It has **all safeguards and controls** in place to ensure high level of protection to citizens during a mass vaccination campaign
  - A robust **monitoring plan** for managing **safety**
  - Clear **legal framework** for evaluation of **emerging efficacy data**
  - **Manufacturing** controls including **batch controls** for vaccines
  - Full **prescribing information** and **package leaflet** with defined conditions for storage and use of the vaccine
  - A **plan** for **use** of the vaccine **in children**
  - **Additional studies or other data** ('conditions') that the company is **legally obliged** to provide with defined **timelines**

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ICMRA and COVID-19 response since April 2020

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- > 30 countries
- Executive level
- WHO Observer

- Forum to support strategic coordination and support public confidence in COVID-19 vaccines and therapeutics
- Bi-weekly Policy TCs ensures sharing of information and promote convergence
- Regular Working Group coordinates technical work streams
  - Vaccine Pharmacovigilance Network, including work on vaccine confidence
  - Regulatory Agility
  - Digital transformation of GCP and GMP inspections and clinical trials
- Workshops to promote convergence in regulatory approached on: responding to virus variants; inclusion of pregnant and lactating women in trials; reinforcing pharmacovigilance collaboration

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Opening our **P**rocedures at **E**MA to **N**on-EU authorities: the **OPEN** Initiative

- Under OPEN WHO and medicines regulators from outside the EU take part in EMA's scientific evaluations
- Drivers: sharing scientific expertise, tackling common challenges, enhancing transparency on regulatory decisions
- Pilot launched December 2020 for COVID-19 vaccines and therapeutics with TGA Australia, Health Canada, MHLW/PMDA Japan, Swissmedic and WHO
- Participate in CHMP assessments and COVID-19 EMA pandemic Task Force
- Experts keep full scientific and regulatory independence, and participate under existing confidentiality arrangements; have no role in final CHMP B/R decision

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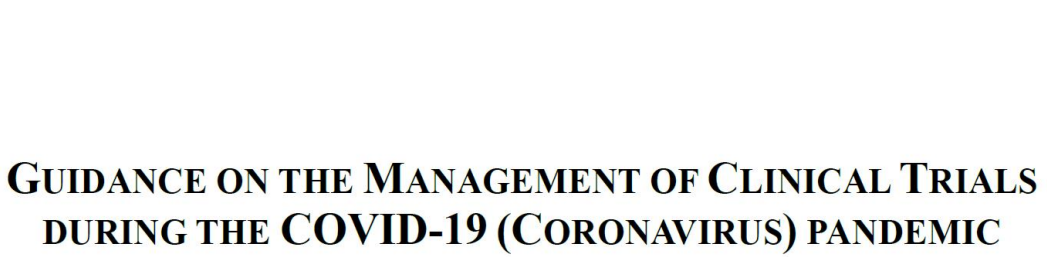

Guidance on the Management of Clinical Trials during the Covid-19 (Coronavirus) Pandemic

Enable continuation of treatment

Ensure Safety reporting

Ensure reliability of trial results, enable trials to continue

Mitigate burden on clinical site staff and facilities and on participants.

Enable management of clinical trials whilst maintain social distancing.

Use Risk assessment

Changes to:

- informed consent process
- distribution of IMP, diagnostics etc
- monitoring and auditing

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Learning from Experience

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Rapid responses and regulatory flexibilities

Pandemic still ongoing and evolving, fast learning and adaptation

Evolving regulatory landscape:

- Use of digital tools has been accelerated
- Dialogue has been significantly increased along development pathway
- Reflect on experience, improve and select what works
- Need feasible, sustainable, tools for longer term, but it will be a new, different, landscape
- We can change now to act by design, and less by reaction to necessity
- Keep regulatory standards high along with speed and innovation

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Key developments

- Complex Clinical Trials:
  - CTFG Reflection Paper: Recommendation Paper on the Initiation and Conduct of Complex Clinical Trials 12 February 2019
  - Ongoing discussions with industry and academia associations and Q&A development – CTFG, EMA, European Commission
- Decentralised Clinical Trials.
  - Ongoing discussions on frameworks and pilots CTFG, EMA, European Commission.

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Redesign our approach to enable innovation in a Rapidly Evolving Ecosystem

Set the foundations to enable innovation by design and not by reaction

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Clinical Trials of the Future – some of the challenges

- Digitalisation – use of more diverse tools and data sources, changing means of interaction between people and information, building trust in the data and in its use
- Ensuring, sufficiently powered (often large), well designed, randomised, clinical trials
- Platform trials and master protocols – maximising the benefit of scientific investigation on a large scale

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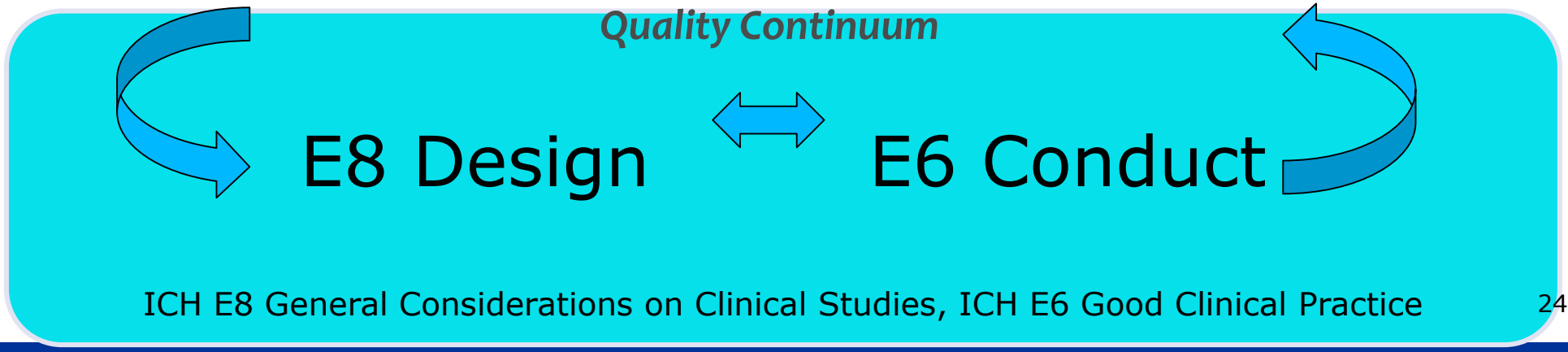
ICH GCP Renovation

- Establish a quality continuum throughout design and conduct. Design that involves engagement with stakeholders including patients and investigators

- The purpose of clinical trials is to generate information to support decision making - their quality must be sufficient to protect participants and generate results that support good decision making

- ICH E8 focus on achieving quality by good design, with a risk based, proportional approach, ICH E8 and E6 need modernising to set the foundation for:

  - future medicines, future trial designs, future technologies, future data sources



ICH GCP Draft Principles

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10- Clinical trials should generate reliable results.

- 10.1 The quality and amount of the information ….sufficient to provide confidence in the trial's results and support good decision making.

- 10.2 Systems and processes …… implemented in a way that is proportionate to the risks to participants and the reliability of trial results.

- 10.3 Tools …..should be fit for purpose, should capture the information required by the protocol, and should conform to principles that ensure reliable results.

- 10.4 Digital systems used for clinical trial purposes should consider the factors critical to their quality in their design and be fit for purpose. To this end, validation of systems, data protection, information technology (IT) security and user management are important elements that should be addressed.

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ICH GCP Draft Principles

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10.5 …efficient and well-controlled processes for managing information … data integrity, traceability, and protection of personal information, thereby allowing the accurate reporting, interpretation, and verification of the clinical trial-related information.

10.6 ……information …retained .. by sponsors and investigators……..to enable reconstruction of the trial conduct and results in order to ensure reliability of trial results.

10.7 The transparency of clinical trials ….includes registration on publicly accessible and recognized databases, and the public posting of clinical trial results.

10.8 The principles …..apply irrespective of the type of media used.

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Digitalisation - Challenges

- Establishing Trust
  - Data provenance, validity (technical and scientific)
  - New data sources
  - Personal data protection – ensure protection whilst enabling clinical trial data to be used well – both are legitimate expectations of trial participants
  - Complex landscape or data generation, collection and analysis, digital communication, remote visits, use of wearables, electronic informed consent
- Need to set standards for use of digital tools and information that are universally applicable, future proof, ensure data trust and participant protection but support innovation and new approaches
- EU GCP IWG Draft Guideline on computerised systems and electronic data in clinical trials - open for comment 18 June to 17 Dec 2021

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/draft-guideline-computerised-systems-electronic-data-clinical-trials_en.pdf

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The benefits of large scale RCTs

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Medicines | Human regulatory | Veterinary regulatory | Committees | News & events | Partners & networks | Abou

International coordination needed to encourage conduct of large, decision-relevant COVID-19 clinical trials Share

Press release 15/05/2020

Regulators are highlighting the need for a comprehensive international coordination mechanism to allow the conduct of adequately powered, randomised controlled trials, which can generate sound evidence on the effects of therapeutics or vaccines against COVID-19. This follows a call made by EMA's Human Medicines Committee (CHMP) for the research community to pool resources into large, well-designed, multi-arm clinical trials to determine which investigational or repurposed medicines would be safe and effective for the treatment or prevention of COVID-19.

Although the scientific community has responded to the COVID-19 challenge in an unprecedented manner, there are concerns about the growing number of COVID-19 stand-alone clinical trials with a small number of participants and observational studies, which might not generate the data required for regulatory decision-making.

- Experience and data in clinical trial registers shows that far too many trials are small, underpowered and poorly designed.
- Fewer, well designed, large RCTs, run multinationally would deliver better information for regulatory and healthcare decision making
- COVID experience has reinforced this message very strongly

Clinical Pharmacology & Therapeutics

REVIEW | Open Access

Clinical trials for Covid-19: can we better use the short window of opportunity?

Hans-Georg Eichler, Marco Cavaleri, Harald Enzmann, Francesca Scotti, Bruno Sepodes, Fergus Sweeney, Spiros Vamvakas, Guido Rasi

First published:14 May 2020 | https://doi.org/10.1002/cpt.1891

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Enabling large trials

- Build and maintain large investigator networks
- Link national and regional investigator networks, at regional and multi-regional level
- Provide infrastructure for the networks, independently of public or private trial sponsors
- Enable trials involving (multiple) public health and or private sponsors
- Build infrastructure for health bodies to sponsor international trials across different jurisdictions and to act as the lead and applicant across all jurisdictions
- Address drivers of small trials – poor funding, lack of network opportunity, need for academic recognition
- How can small trial proposals be referred to large trial groups?

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Platform trials

- Some clear successes during COVID19
- Challenges:
  - Running platform trials across multiple countries and regions as a clear single protocol with a clear sponsor to apply for and manage the clinical trial
  - Managing trials with products in development and established products (registration goal and therapeutic guidance/repurposing of established medicines
  - How much can be managed in a single platform trial
  - Scientific and methodology challenges
  - Objectives – medicine registration, repurposing….
  - Infrastructure and trial management
  - Clinical trial authorisation – thinking outside of the box – e.g. is a platform trial one or several, grouped, trials for purposes of

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Change the way we all work – don't add more to the status quo.

Change Management is the greatest challenge

– adjusting behaviors, attitudes – away from preconceived ideas and interests – and on to a new, better, way of working.

"Perfection is achieved not when there is nothing more to add but when there is nothing left to take away" *Antoine de Saint-Exupéry*

"Everything should be made as simple as possible but not simpler" *Albert Einstein*

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Build future for clinical trials by design

Develop standards for digital tools used in clinical trials. Enable new data sources

Build trust in the validity of data and in protection of participant privacy

Ensure properly powered, large, randomised clinical trials

Enable large investigator networks, and link networks between regions. Develop infrastructure to support them.

Develop the science and regulatory models for platform trials. Enable them to work across countries and regions

And now the discussion

Further information

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Keynote 2: Aligning global clinical trial requirements

Ginny Beakes-Read,

Executive Director, Global Regulatory and R&D Policy, Amgen

ALIGNING GLOBAL CLINICAL TRIAL REQUIREMENTS

Ginny Beakes-Read
Global Regulatory and R&D Policy

June 24, 2021

AMGEN®

Amgen Proprietary – Not for Further Distribution

BACKGROUND

- Amgen used SmartSheet tool to collect content and Amgen interpretation of global regulatory guidelines

- Colors in charts visually illustrate Amgen interpretations of regulatory guidance, such as:
  - Additional procedural steps needed
  - No guidance available
  - Guidance permits a flexible approach

Amgen Proprietary – Not for Further Distribution

COVID-19 Clinical Trial Regulatory Guidance

Clinical Trial Priority Topics – Comparison Charts

All Countries

EU Countries

Intercontinental

JAPAC

ICMRA Health Authorities

Key Health Authorities

Resources

- COVID-19 Regulatory Guidance Tracker (View Only * w / links to country specific guidance - GENERAL USE)
- COVID-19 Regulatory Guidance Tracker (Admin Only)

Contacts

Amgen Lead: Ginny Beakes-Read

Design, Content Input, & Review: Laura Bloss, Jae Chang, Heloisa Fostinone, Melissa Eisen, Kulbir Malek, Tamura Della Mussia

Reporting and Dashboard: Maddie Neisser, Heather Case

Regulatory / IRB / EC Communications

- Enrollment Pause/Restart w/Comments- Submission to HA
- Enrollment Pause - Submission to HA
- Enrollment Restart - Submission to HA
- Enrollment Restart Submission - HA vs EC/IRB
- Protocol Deviations - Required Actions
- Temporary Use of Telemedicine - Submission to HA
- Wet Ink Signature Requirement

Sub-Topic Metrics

Study Visits / Procedures

- Alternative Methods of Consent - Permitted?
- Use of Local Labs
- Guidance Permits Remote SDR/SDV

Sub-Topic Metrics

Investigational Product / Shipment

Safety / Efficacy

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COMPARISON GRID OF SELECT HEALTH AUTHORITIES

Country / Health Authority	Enrollment Restart - Submission to HA	Temp. Use of Telemedicine - Submission to HA?	Protocol Deviations - Required Actions	Guidance Permits Remote SDR/SDV	Local Labs - Submission to HA?	Alternative Methods of Consent - Permitted?	Alternative Means of Drug Delivery - Permitted?
Australia (CTPRG / TGA)	Not Required	Depends on Nature of Deviation or Modification	Notify and/or submit in bulk	Yes	Permitted; Requires notification	Permitted	Permitted; No notification required
Belgium (FAMHP)	Notification Only	Depends on Nature of Deviation or Modification	Additional considerations. See comments.	No	Not addressed in guidance	Permitted	Permitted; Additional notification/submission considerations. See comments.
Canada (Health Canada)	Notification Only	Not Required	Notification	Not addressed in guidance	Permitted; No notification required	Requires notification and/or approval	Permitted; No notification required
European Union (EMA)	Notification Only	Not Required	Follow Sponsor's standard procedures	Follows EMA Guidance Under special circumstances	Permitted; Requires notification	Requires notification and/or approval	Permitted; Additional notification/submission considerations. See comments.
Germany (BfArM / PEI)	Submission; Approval Required	Depends on Nature of Deviation or Modification	Not addressed in guidance	Under special circumstances	Permitted; Additional notification/submissic considerations. See comments.	Permitted	Permitted; Additional notification/submission considerations. See comments.
Japan (PMDA)	Not Required	Not Required	Document	Not addressed in guidance	Permitted; No notification required	Not addressed in guidance	Permitted; No notification required
UK (MHRA)	Not Required	Not Required	Document	Under special circumstances	Permitted; No notification required	Additional considerations	Permitted; No notification required
United States (FDA)	Not Required	Depends on Nature of Deviation or Modification	Document	Yes	Permitted; Additional notification/submissic considerations. See comments.	Permitted	Permitted; Additional notification/submission considerations. See comments.

Legend: Colors and shades vary from Dark Green (most permissive or flexible) to Dark Red (most restrictive, or most process required). Yellow indicates that no guidance is provided.

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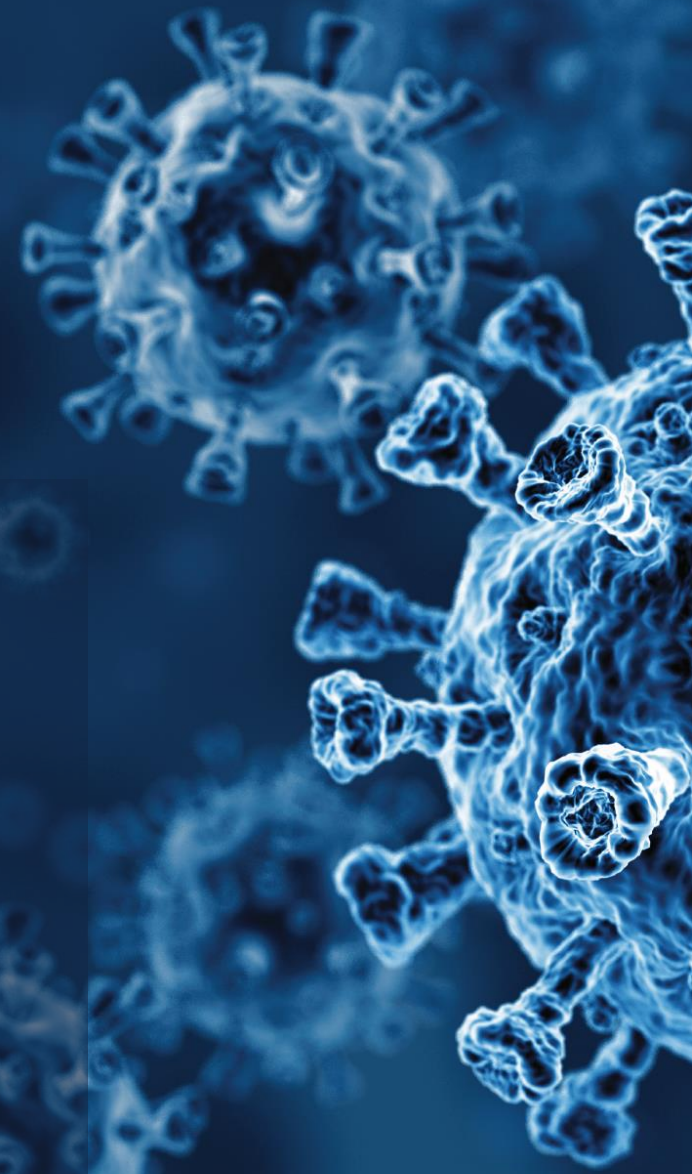

First Panel:

Enabling regulatory flexibilities in a global context

10:45 AM – 11:40 AM EDT

Panelists

Taras Carpiac
Amgen

Richard Moscicki
PhRMA

Barbara Bierer
MRCT Center

Lauren Hartsmith
Advarra

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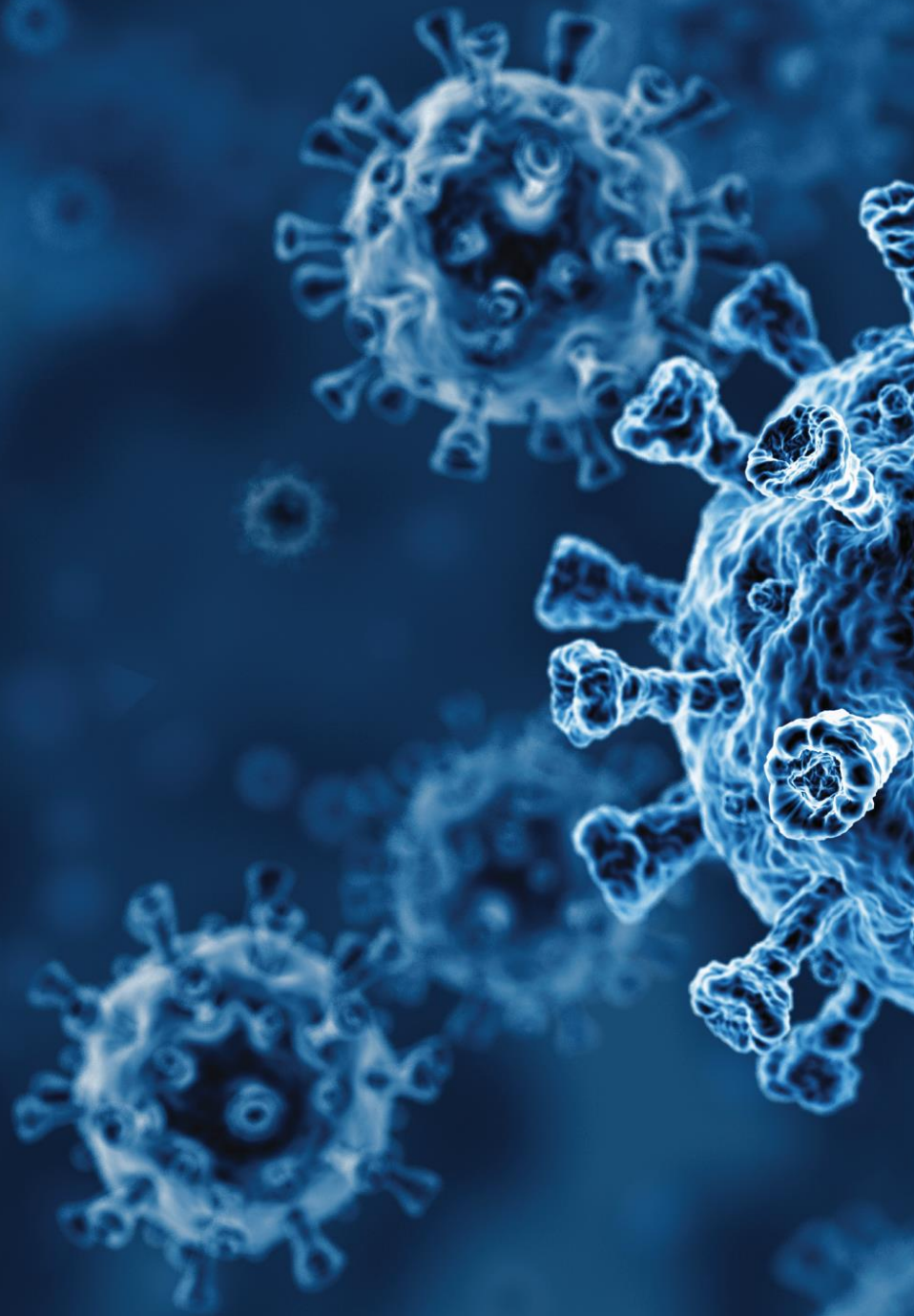

BREAK
10 min

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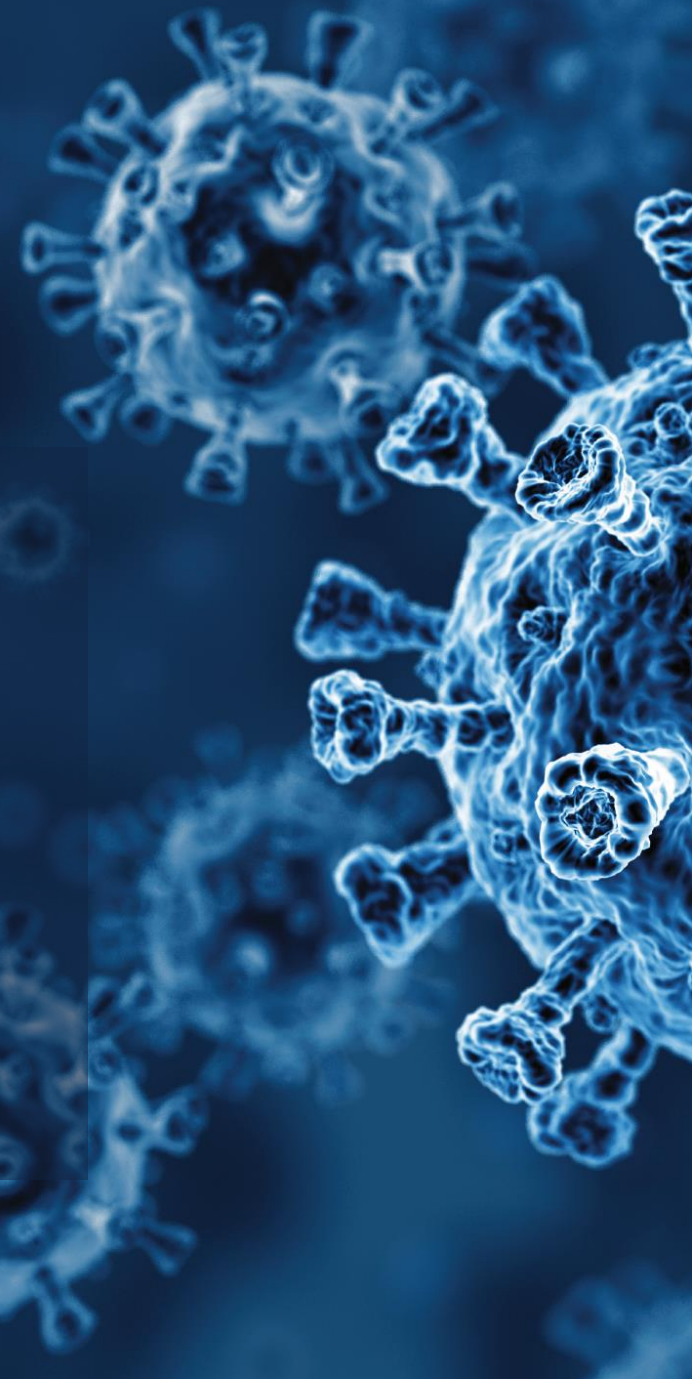


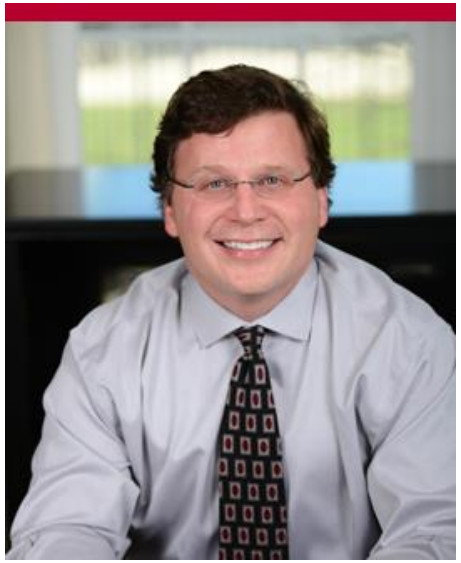
Second Panel:

Regulatory cooperation and communication and issues of governance in a global pandemic

11:50 AM – 12:45 PM EDT

Panelists

M. Khair ElZarrad
US FDA



Owen Fields
Pfizer

Mark Barnes
MRCT Center &
Ropes & Gray

Steven Kern
Bill & Melinda
Gates Foundation

Fergus Sweeney
European
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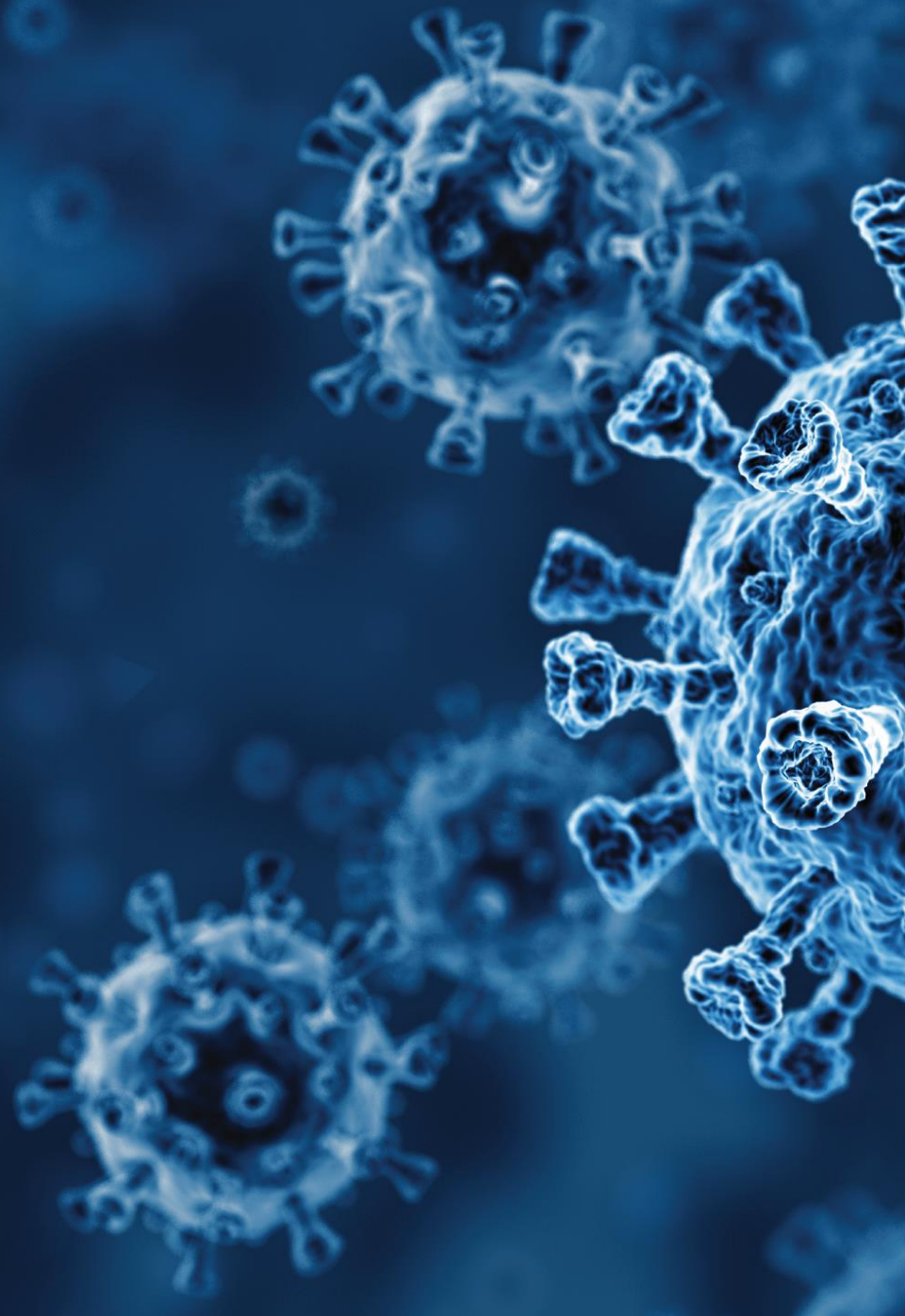
Discussion and Wrap-up



Recordings Available

- https://mrctcenter.org/news-events/reimagining-clinical-trials-learning-from-covid-19/

The **first meeting (June 16, 2021, 10AM-1PM EDT)** will focus on permissible flexibilities to study conduct and coordination, including site flexibilities, decentralized trials, and other changes, and the implications for the clinical research workforce in this new environment. The **second meeting (June 24, 2021, 10AM-1PM EDT)** will focus on regulatory flexibilities, international cooperativity, and governance. The meeting is open to all interested stakeholders and to the public.

REGISTER for the first meeting, June 16, 2021, 10 AM – 1 PM EDT

REGISTER for the second meeting, June 24, 2021, 10 AM – 1 PM EDT

June 16, 2021: 10:00 am - 1:00 pm EDT

+ Agenda

+ Speaker Information

+ June 16, 2021 Webinar Recording, Slides and Transcript

June 24, 2021: 10:00 am - 1:00 pm EDT

+ Agenda

+ Speaker Information

Planning Committee

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MULTI-REGIONAL CLINICAL TRIALS

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Thank You