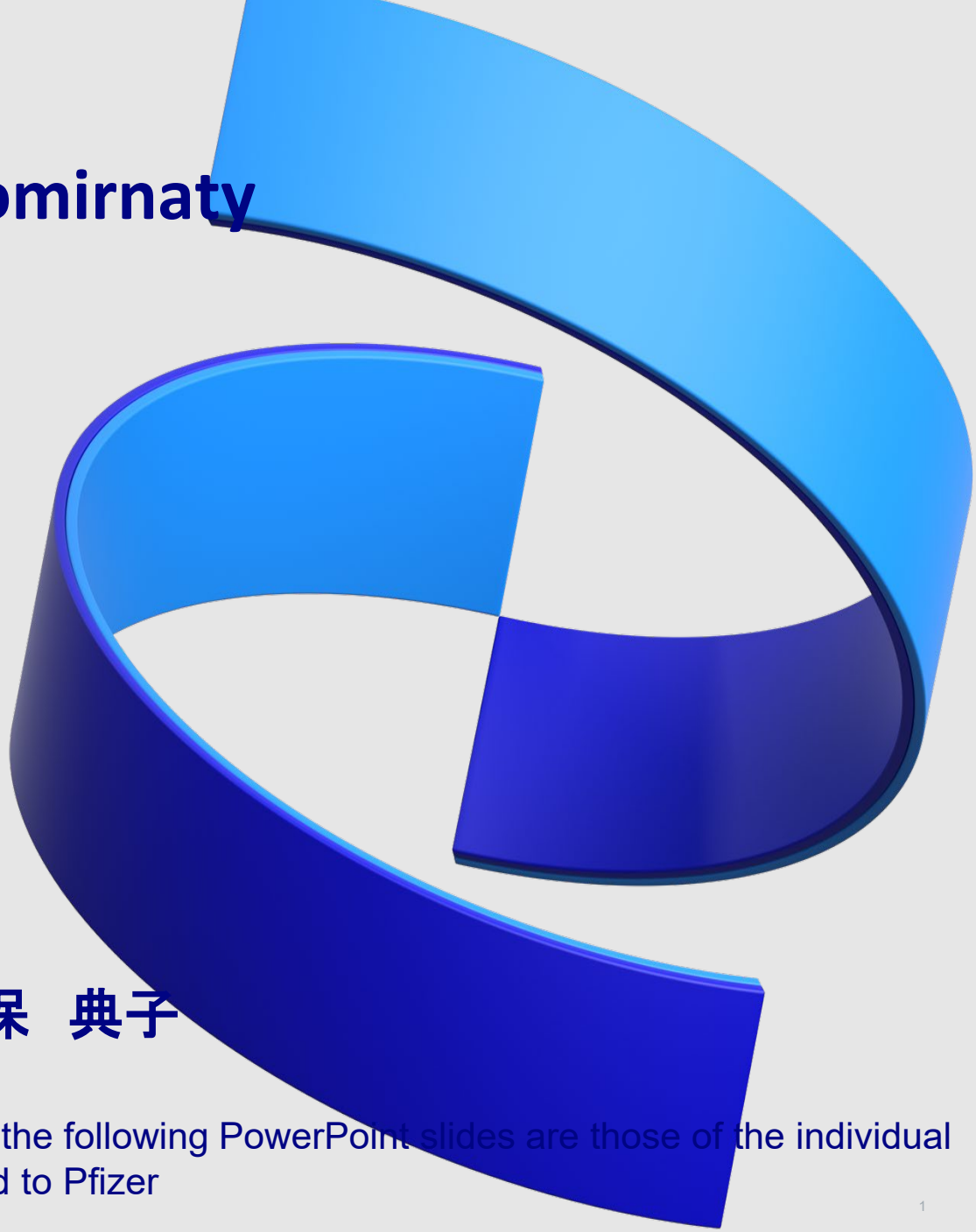
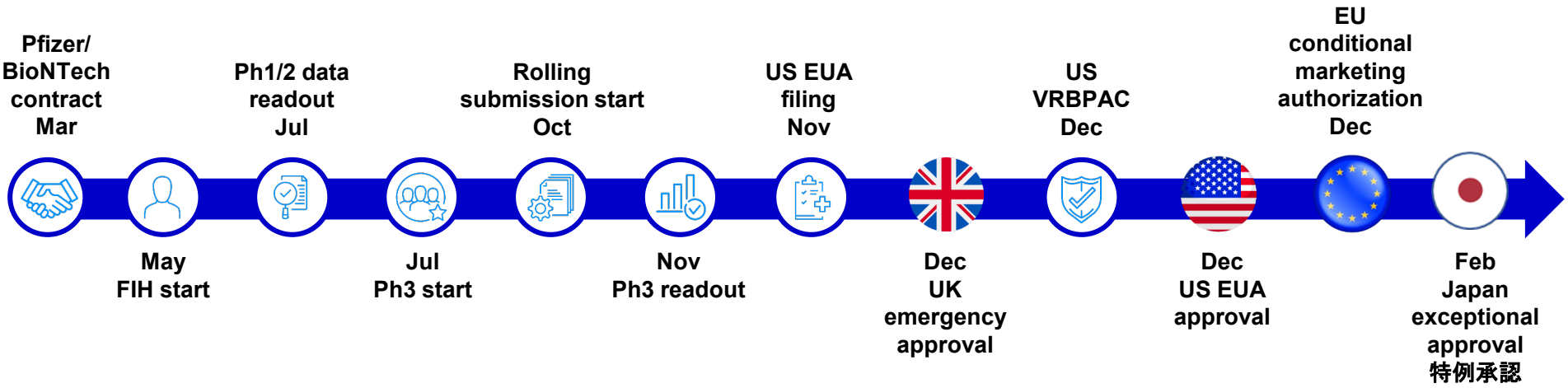
Development of Comirnaty
コミナティの開発



Noriko Morikubo　森久保　典子
Pfizer R&D

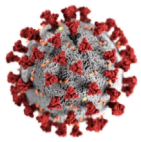
The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to Pfizer

Overview of Comirnaty Development



- Authorized or approved in 92 countries as of Aug 31, 2021
- Continuous process improvements, expansion at current facilities, and addition of new suppliers & contract manufacturers to supply approximately 2.5B doses by end of 2021

Japan indication:



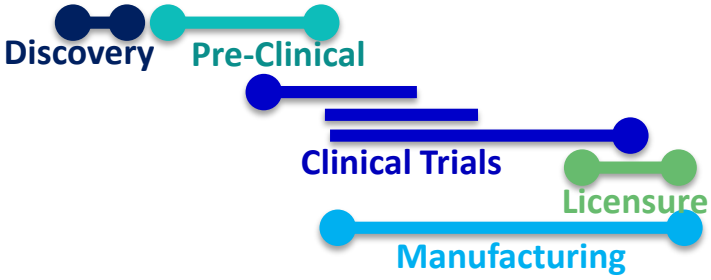
Prevention of infectious disease caused by SARS-CoV-2

Individuals 12 years of age and older

Duration of COVID-19 Vaccine Development

コミナティの開発 Comirnaty Development

10 months*



典型的なワクチン開発 Typical Vaccine Development

10 years

* From pre-clinical start to US EUA approval

Factors that Led to Acceleration

- **科学的な基盤　Scientific foundation**
  - Abundant expertise in vaccines and infectious diseases (SARS, MERS)
  - mRNA and viral-vector platforms ready for use
- **科学に基づく規制当局の柔軟な判断 Science-based flexibility in regulatory agencies**
  - Accepted conduct of animal challenge model and assessment of enhanced disease in animals in parallel with clinical trials
  - Accepted innovative trial design by combining Ph1/2/3 using Bayesian statistics
- **革新的な治験のオペレーション Innovation in clinical trial operations**
  - Opened trial sites globally in light speed in emerging hot spots of COVID-19 while considering diversity and data quality
  - Enabled automation in data management

Factors that Led to Acceleration

- **リアルワールドエビデンスの活用　RWD/RWE utilization**
  - Utilized RWD/RWE for post-marketing safety assessment
  - The incredibly fast development and rollout of the vaccines would not have been possible without the critical contributions of real-world evidence (RWE)
- **リスクを伴う資金投資　Funding at risk**
  - Manufacturing started while clinical trials were still underway
- **優先度　Priority**
  - Priority review in regulatory agencies
  - Priority decision making in companies

Situation in US

EUA is not the sole factor that led to acceleration

Specific to pandemic

- Funding at risk
- Priority
- Scientific foundation
- Science-based flexibility in regulatory agencies
- Innovation in clinical trial operations
- RWD/RWE utilization

Normal

Operation Warp Speed

Deliver 300 million doses of a COVID-19 vaccine by **January 2021,** creating a safe and effective vaccine

Emergency Use Authorization (EUA)

The 21st Century Cures Act in 2016

Research

- Investment to NIH to promote science research

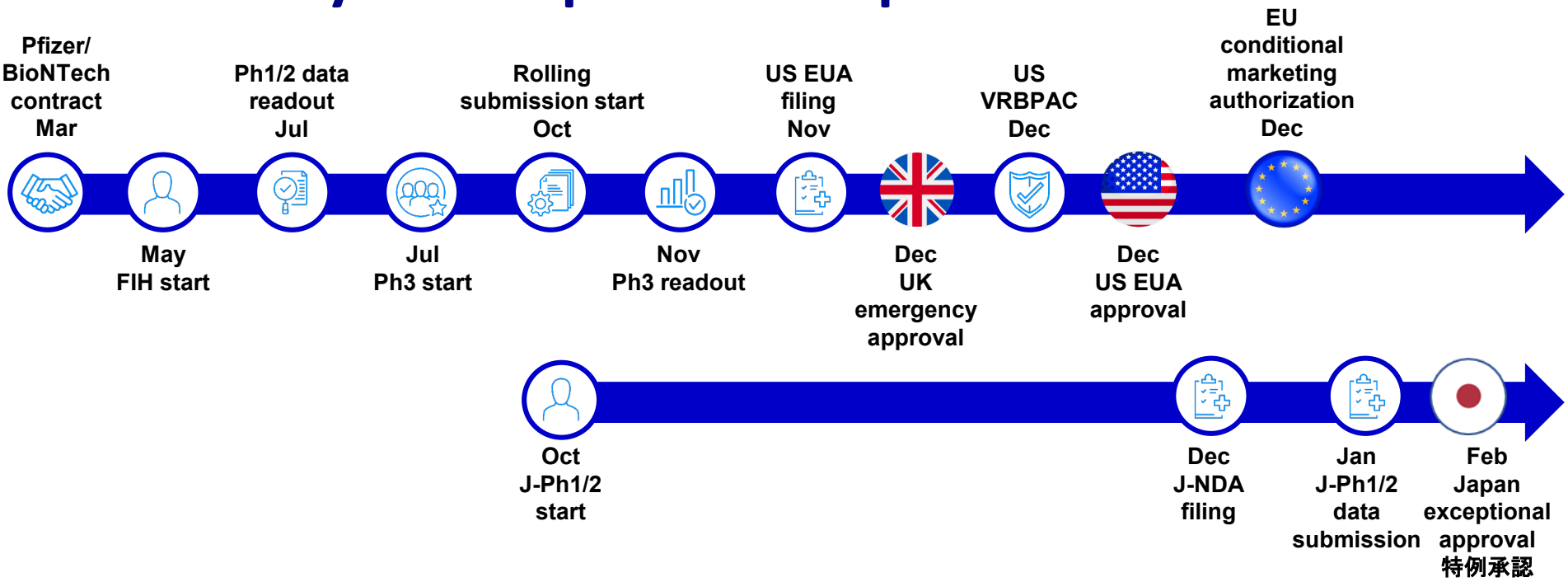
Getting Treatments to Patients more quickly

- **Innovation and Fastest regulatory review** for vaccines
- Broader use of **"innovative statistical methods in clinical protocols"**
- **Promote to use RWD/RWE to monitor postmarket data to make regulatory decisions.**

EUA / Exceptional Approval of Comirnaty

	US		Japan
	EUA **緊急使用許可**	**BLA** **製造販売承認**	**Exceptional Approval** **特例承認**
申請資料の形式 Submission Style	Summary document	CTD	CTD (in Japanese)
臨床データ **（COVID-19 ワクチンの場合）** Clinical data package	G-Ph1/2/3 Safety: 2M post dose 2	G-Ph1/2/3 Safety: 6M post dose 2	G-Ph1/2/3 Safety: 2M post dose 2 J-Ph1/2
GMP関連調査 GMP inspection	Not required	Required	Required
国家検定 National testing for domestic release	Not required	Required	Required

Comirnaty Development in Japan



Acceleration of regulatory review

- Rolling submission started in Oct
- J-NDA review, GCP/GMP inspection started prior to formal filing
- Pre-approval testing and preparation for national testing started prior to formal filing in collaboration with NIID

Factor specific for Japan

- J-Ph1/2 data required for approval

Need for Greater Regulatory Agility for Stable Supply

Impact on supply chain

COVID-19 created unprecedented constraint on global biopharmaceutical supply chain – raw materials suppliers, manufacturers, wholesalers, distributors

Need for greater regulatory agility – Enhance collaborative review & regulatory reliance practices

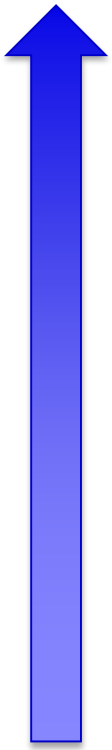
- Develop regulatory reliance practices for inspections of manufacturing facilities of COVID-19 vaccines
- Establish collaborative review arrangements for supplements/ variations for post-approval changes of COVID-19 vaccines
- Adopt reliance practices for queries issued by national regulatory agencies and manufacturer's responses for supplements/variations
- Eliminate the need for duplicative national testing

Biopharmaceutical Industry Statement on ICMRA workshop

1) Streamline stability testing requirements
2) Embrace alternate process validation approaches
3) Increase utilization of and harmonize approaches to inspection alternatives
4) Enhance collaborative review and reliance practices for initial registration and post approval submissions.

Building On Pandemic Experience to Bring Vaccines Faster to Japan

Emergency



Normal

緊急時の考え方

- Develop reliance practices for GMP inspections and reviews
- Eliminate need for duplicative national testing
- Reconsider extent of Japanese data for exceptional approval

医薬品開発環境の整備

- RWD/RWE utilization
- Innovation in clinical trial operations
- Science-based flexibility in regulatory agencies
- Scientific foundation

Breakthroughs that change patients' lives

Always thriving to make the best decision from pre-pandemic phase globally