Regulatory Flexibilities in CMC Review on Vaccines under the COVID-19 Pandemic

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Pharmaceuticals and Medical Devices Agency
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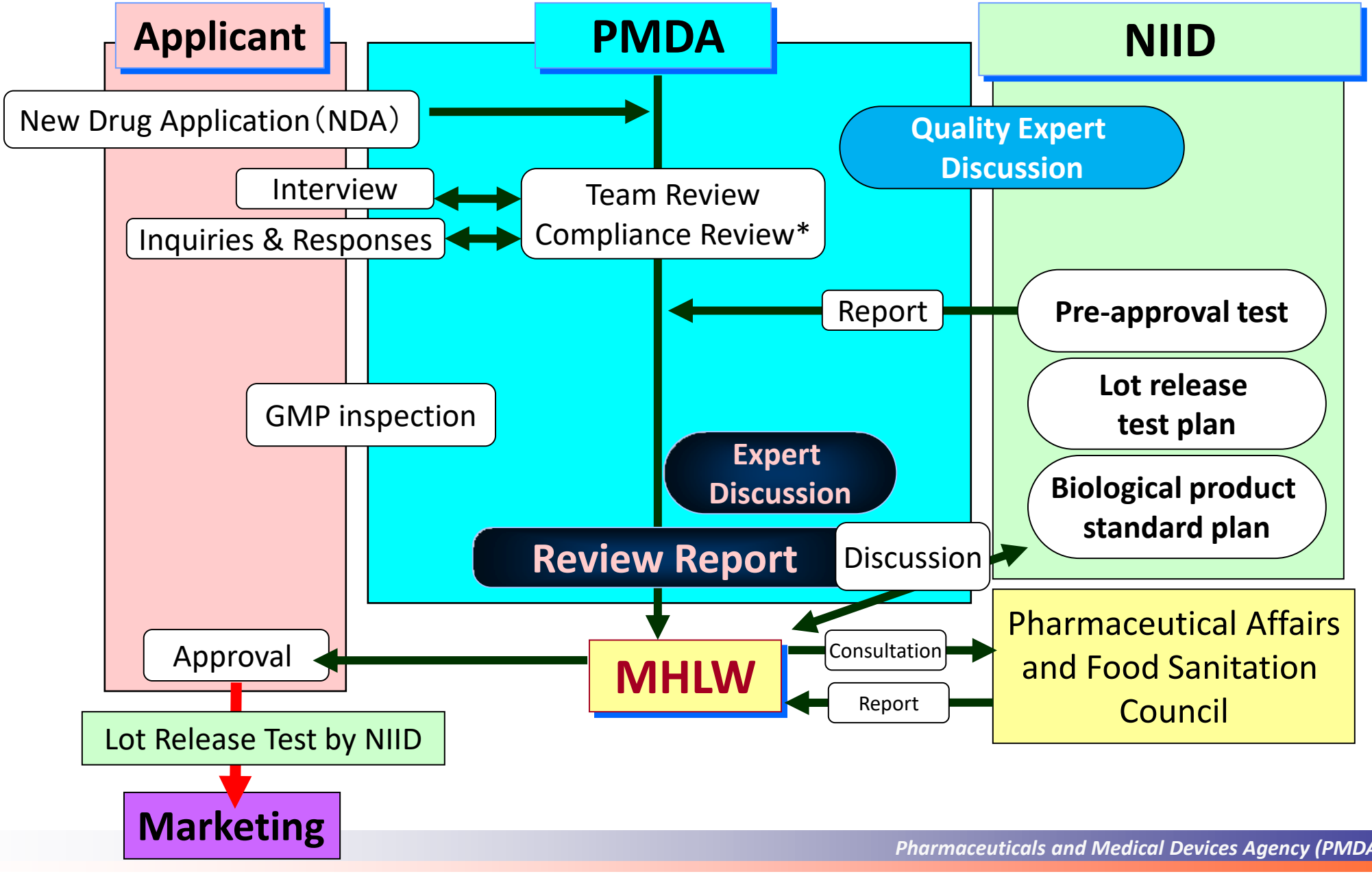
Today's Topics

1. Review prcess of vaccines

2. Regulatory flexibilities in review on COVID-19 vaccines

3. Stability test (feedback from the consultation)

Vaccine Review Process and Lot Release Test



Special Approval for Emergency (SAE)

Under article 14-3 of the PMD Act,

a certain medical product may be approved when:

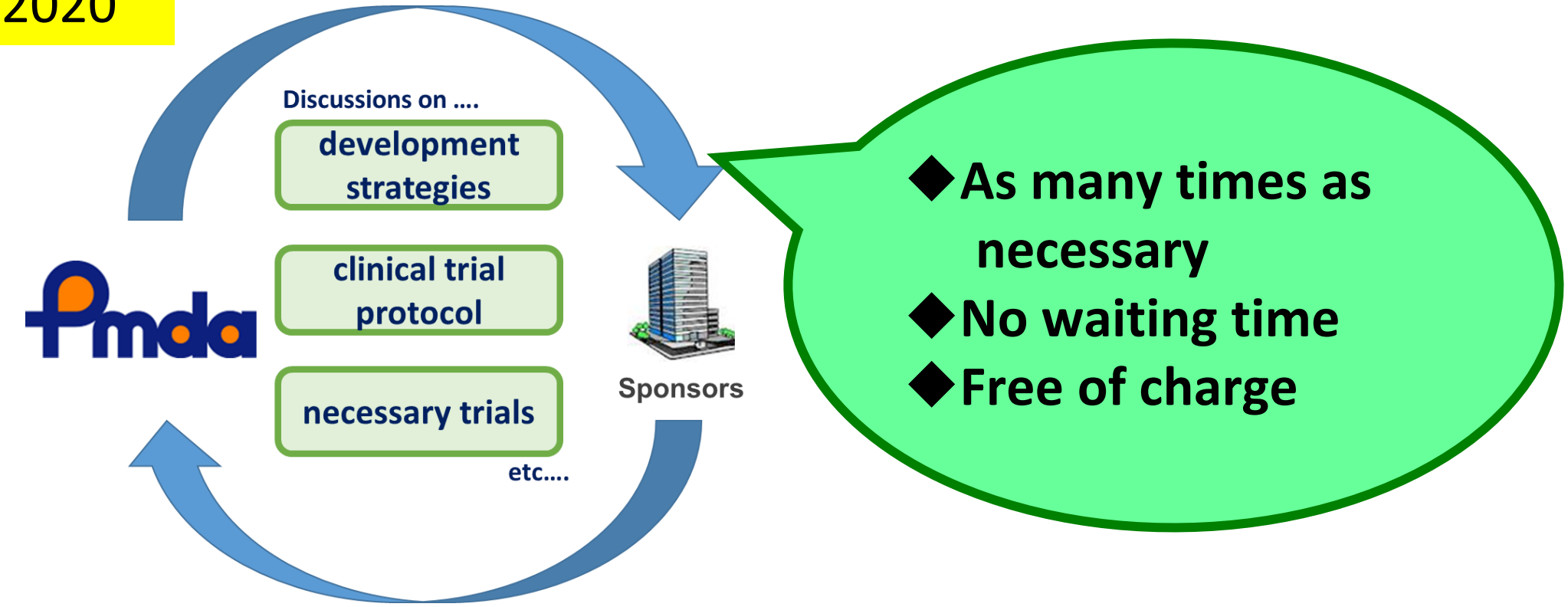
1. an emergency situation requires an unapproved medical product to be used to prevent damage to the public health caused by the spread of diseases
2. such emergency situation cannot be managed appropriately by any means other than the use of the unapproved product, and
3. such product is legally available in a country with a regulatory system for medical products that is equivalent to Japan

- GlaxoSmithKline K.K.: Arepanrix (H1N1) Intramuscular Injection
- Novartis Pharma K.K.: Cell-culture Derived Influenza A (H1N1) Emulsion HA Vaccine "Novartis" for Intramuscular Injection

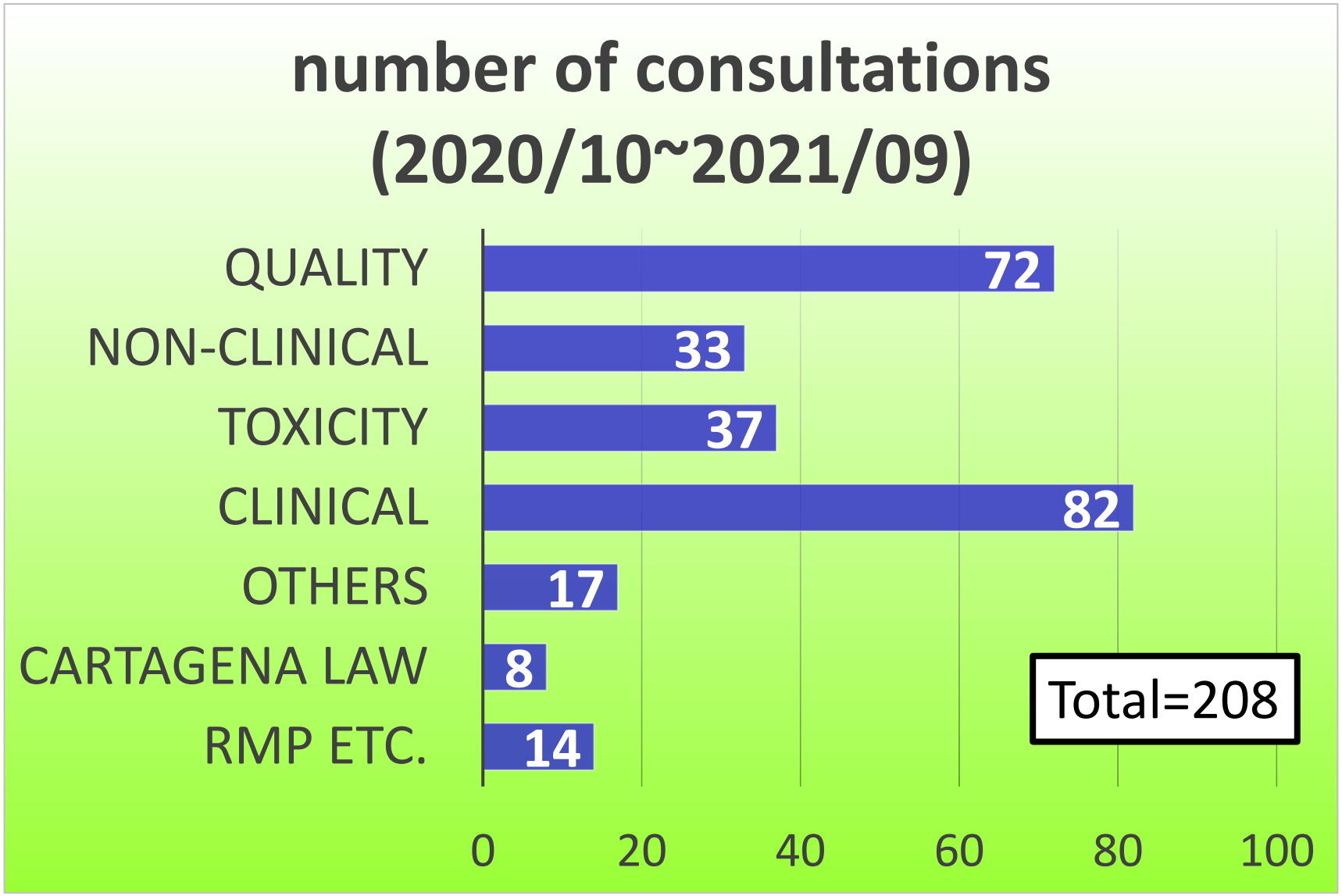
2010

Free Scientific Advice for COVID-19 Vaccines Development

October 1, 2020



Streamlined development for COVID-19 products


number of consultations
(2020/10~2021/09)
QUALITY
NON-CLINICAL
TOXICITY
CLINICAL
OTHERS
CARTAGENA LAW
RMP ETC.
72
33
37
82
17
8
14
Total=208
0
20
40
60
80
100

Timeline for SAE of First COVID-19 Vaccine in Japan

December 2020

Authorization/Approval for use was granted in UK, Canada, USA etc.

18 December 2020

Regulatory Submission by Pfizer Japan Inc.

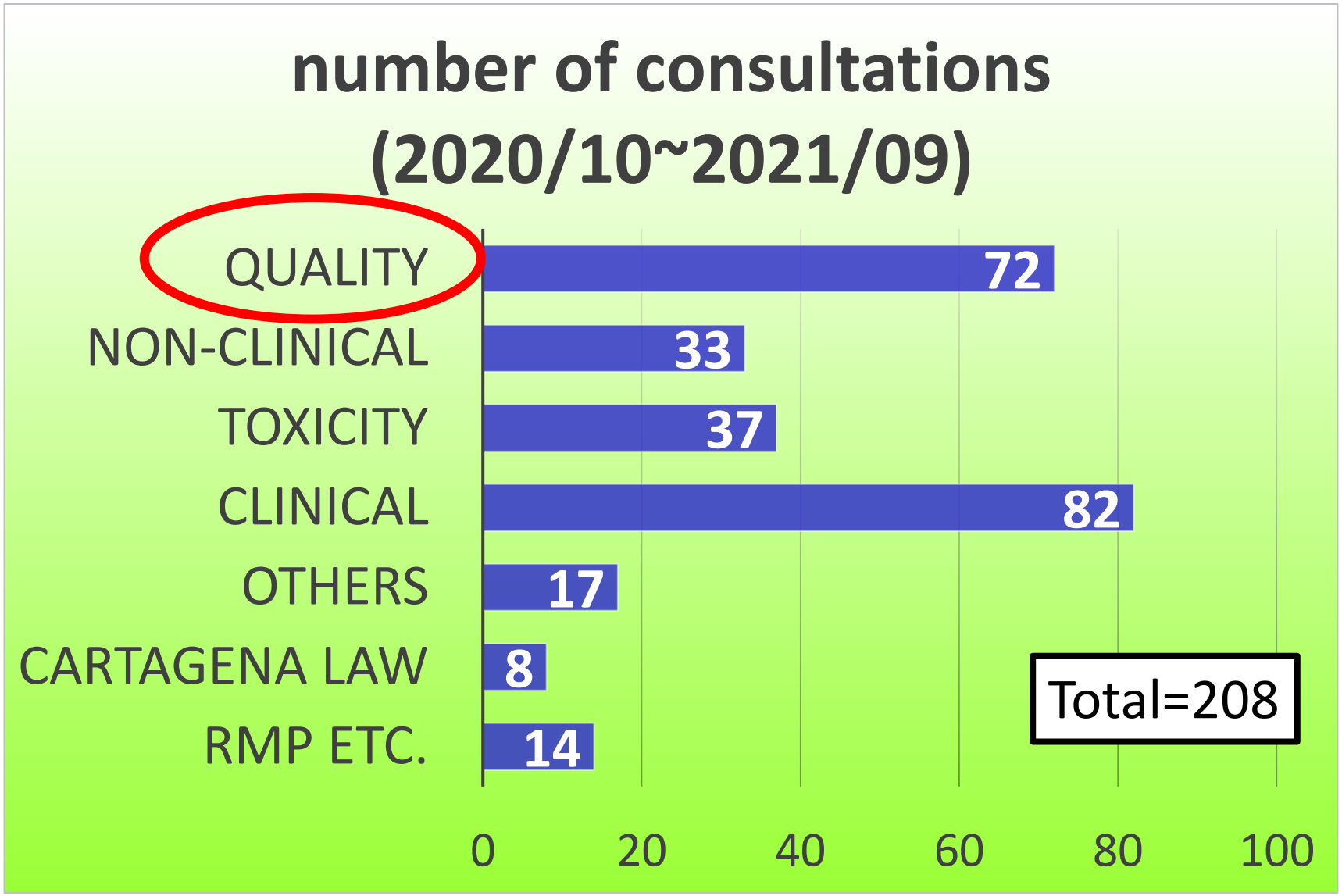
2 months

PMDA prepared the report of available information, approval conditions, etc..

Discussion by Pharmaceutical Affairs and Food Sanitation Council of the MHLW

14 February 2021

SAE of Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2)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Feedback from the consultation(1/2)

What is needed at least to determine the shelf life?

- Specification（a list of tests for drug products）
  - ✓ Potency test, Sterility Test, Foreign insoluble matter test for injections, Insoluble particulate matter test for injections etc.

- Manufacturing Process
  - ✓ Stability test data should be produced using the same procedures that simulate the final process used for commercial batches.

Feedback from the consultation(2/2)

Another topics on the shelf life

- Additional manufacturing sites
  - ✓ Comparability
  - ✓ Stability testing(planning)

- platform