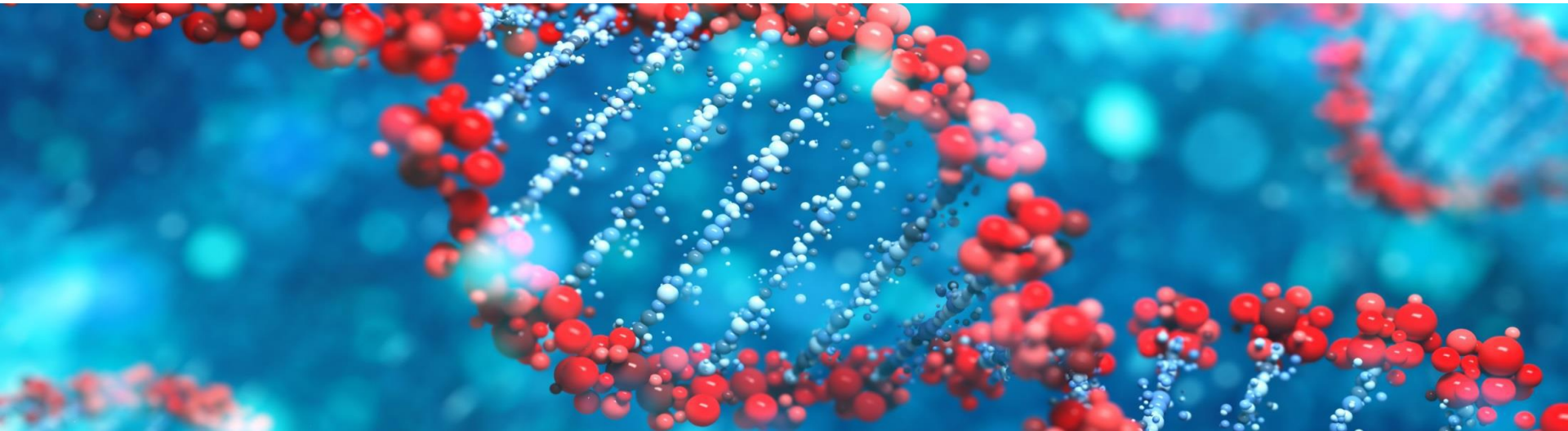
Roche Strategies and Learnings for Early Phase Clinical Trials

Goh, Siew Wei

Country Study Manager/ Local Vendor Manager, RSPL

17 April 2018



Agenda

Roche Strategies for Early Phase Clinical Trials
- **xREDs (Research & Early Development)**
- **imCORE network**
- **MORPHEUS**

Learnings and Experience Sharing for Conduct of Early Phase Clinical Trials
- **Study Feasibility and Site Start-up**
- **Study Conduct**

SAPI Clinical Trials Working Group

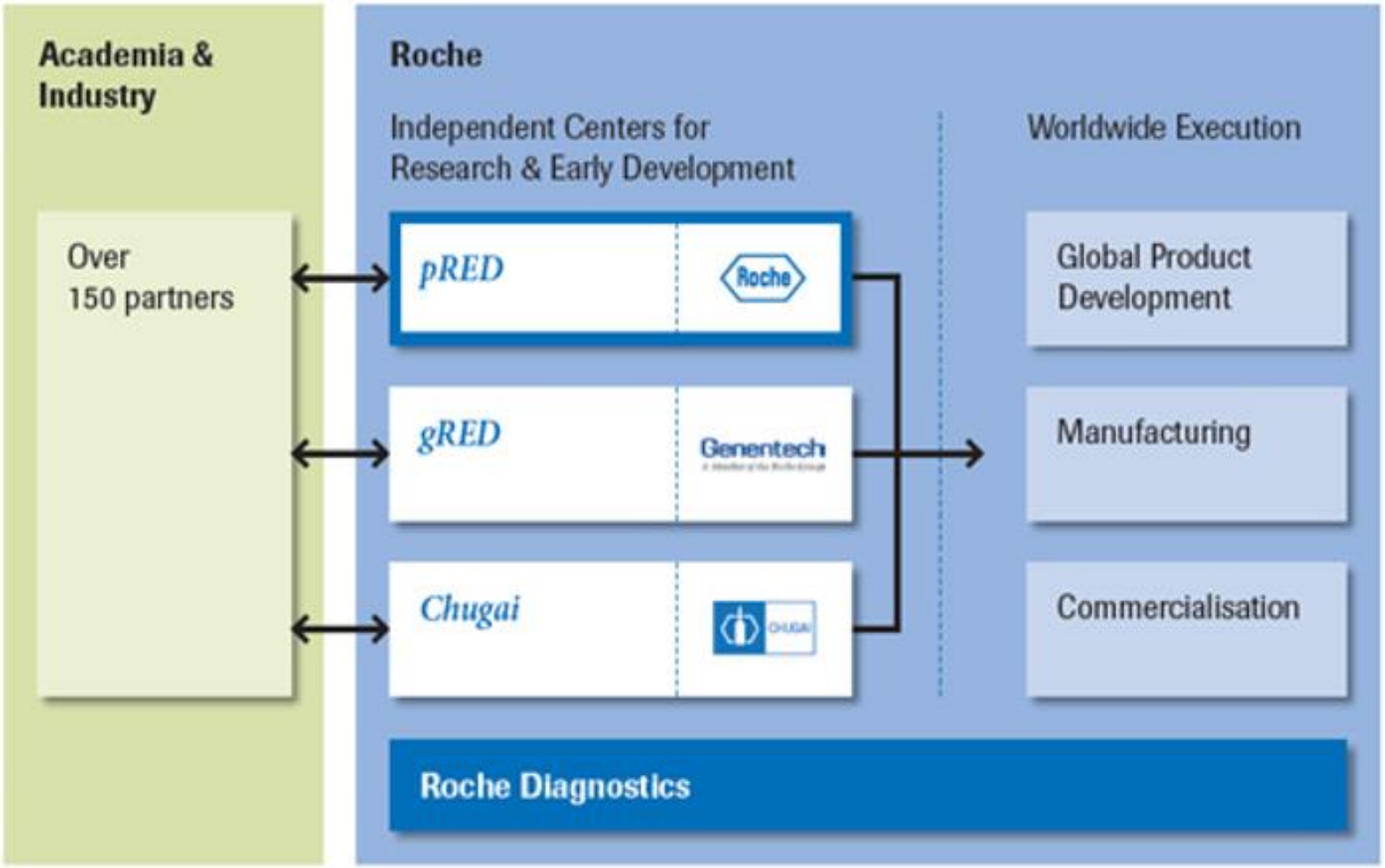
Agenda

Roche Strategies for Early Phase Clinical Trials
- **xREDs (Research & Early Development)**
- **imCORE network**
- **MORPHEUS**

Learnings and Experience Sharing for Conduct of Early Phase Clinical Trials
- **Study Feasibility and Site Start-up**
- **Study Conduct**

SAPI Clinical Trials Working Group

Roche Group


Academia & Industry
Over 150 partners
Roche
Independent Centers for Research & Early Development
pRED
Roche
gRED
Genentech
Chugai
Worldwide Execution
Global Product Development
Manufacturing
Commercialisation
Roche Diagnostics

imCORE (immunotherapy Centers of Research Excellence)

- One of the largest of its kind, the imCORE Network was launched in Washington DC in November 2016 to bring together a large global community of leading experts in cancer immunotherapy who share ideas and work together.
- The Network's membership currently involves 26 leading cancer research institutions from 10 countries across the world. Experts from these centres of excellence, as well as from Roche, are working together to identify and prioritise the most promising new treatment approaches in cancer immunotherapy.

imCORE (immunotherapy Centers of Research Excellence)

- imCORE research is being performed within a common scientific framework that encourages pre-clinical, clinical and translational research to accelerate progress in the cancer immunotherapy field, with the ultimate goal of improving treatment outcomes for people with cancer.

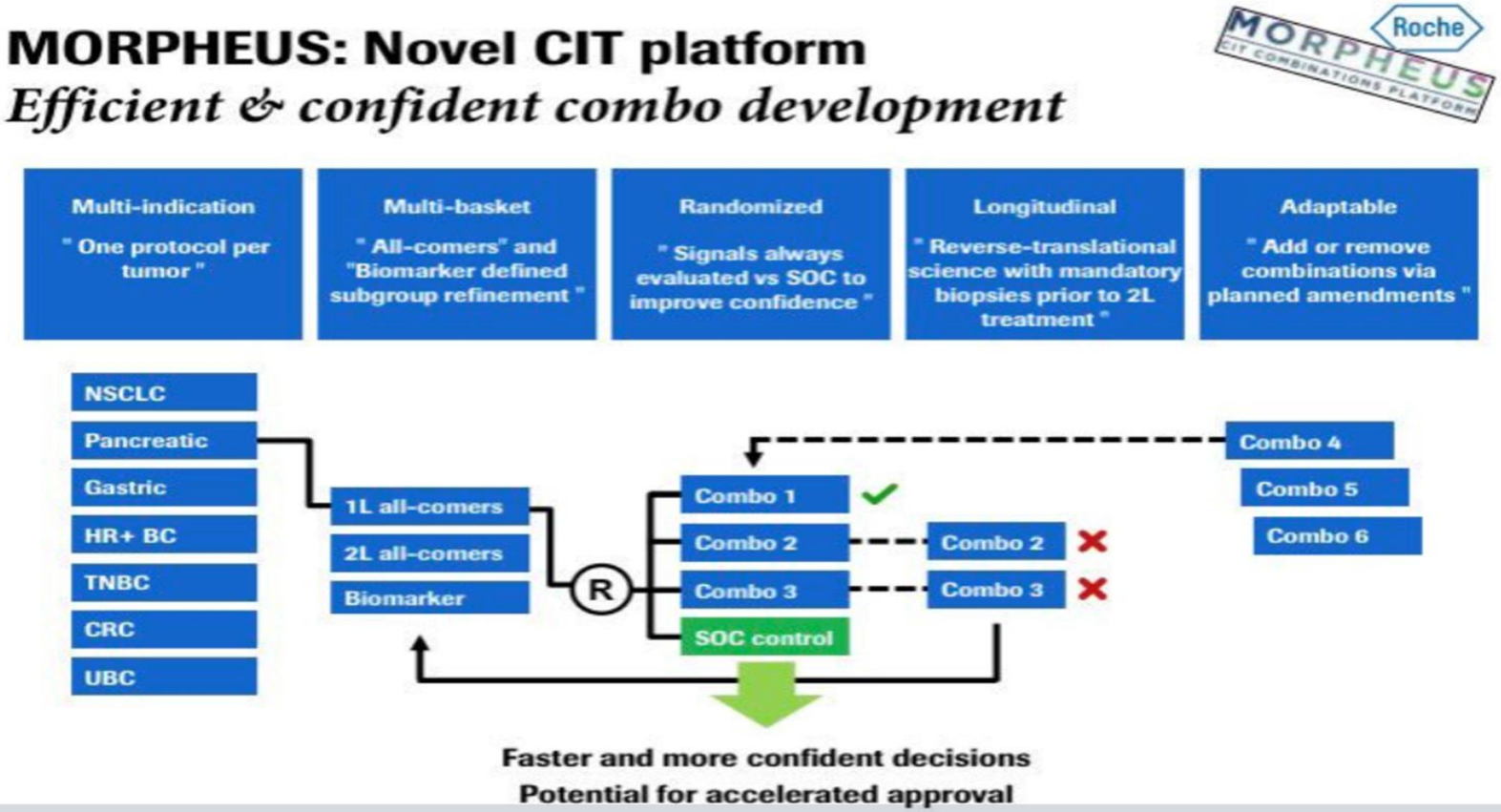
- Expediting the clinical trials process is essential in order to provide patients with faster access to new treatments. Under imCORE's collaborative model, operational processes, patient enrolment and collection of data are streamlined. These improvements have allowed investigators across all study sites to see the benefits with respect to shorter study timelines and quality of data.

imCORE (immunotherapy Centers of Research Excellence)

- With over 40 collaborative research projects already underway since imCORE's launch, and proposals for many more projects currently under consideration, the imCORE Network is already showing early signs of promise for advancing cancer immunotherapy research and finding potential cures for cancer.
- Roche has a long-term commitment to the imCORE Network, and is investing up to 100 million Swiss Francs to support research collaborations.

MORPHEUS

- MORPHEUS is a phase Ib/II adaptive development platform established by Roche to assess the efficacy and safety of combination cancer immunotherapies



Agenda

Roche Strategies for Early Phase Clinical Trials
- xREDs (Research & Early Development)
- imCORE network
- MORPHEUS

Learnings and Experience Sharing for Conduct of Early Phase Clinical Trials
- **Study Feasibility and Site Start-up**
- **Study Conduct**

SAPI Clinical Trials Working Group

Study Feasibility and Study Start-up

- Sponsors
  - Well written protocol
  - Clearly specify facilities required
    - Inpatient or outpatient
    - IMP
      - Preparation (any special requirements e.g. aseptic?)
      - Storage (before and after reconstitution)
      - Administration (pumps, infusion line compatibility, Blinding vs unblinding)
    - Sample storage and shipment
      - Lab manual (storage and processing instructions)
  - Communication with potential PIs

Communicate any requirement changes to protocol and facilities immediately to sites!

Study Feasibility and Study Start up

- Institution
  - Ongoing assessment to ensure facilities required are met
  - Logistics
    - Decision of IMU vs hospitalisation, budgeting
    - Commissioning of equipments supplied or sourced by sponsor
    - Training of staff for the equipments and materials supplied
  - Study Workflow
    - Clear workflow and responsibilities of various parties (Inv, SC, Nurses, Pharmacist)
  - Highly committed Investigators and Site Staff
    - Think out of box for alternative solutions

Involvement and Collaborations of all parties right from the beginning!

Study Conduct

- Patient Recruitment
  - Due to competitive recruitment, Send screening form to SMT to secure a screening slot asap
  - Reply promptly on any clarifications with regards to patient eligibility
- Close communications/ interactions between Study Management Team and Investigators
  - Active discussion on patient condition, safety and efficacy th[illegible]hout study teleconferences with Investigators

Close Collaborations between SMT and Investigators/ Sites!

Agenda

Roche Strategies for Early Phase Clinical Trials
- xREDs (Research & Early Development)
- imCORE network
- MORPHEUS

Learnings and Experience Sharing for Conduct of Early Phase Clinical Trials
- Study Feasibility and Site Start-up
- Study Conduct

SAPI Clinical Trials Working Group

SAPI Clinical Trials Working Group

- Set up on 24 Oct 2017 with members from 9 major Pharmaceutical/ CRO companies, to facilitate initiation and conduct of clinical trials in Singapore, to maintain/ increase Singapore's competitiveness for clinical trial placements

- Reduction of Time to Initiation
  - Clinical Trial Agreement (In progress)
    - Adopting Best Industry Practice from Australia
    - Alignment and development of a consistent Clinical Trial Agreement Template to be used across institutions and sponsors for all studies
    - Reduces agreement negotiation time and allows faster execution of CTA
  - Streamlining of Cost (to come)

Key Message

Commitment & Collaborations are the Key Factors for the Successful Conduct of Early Phase Clinical Trials!

Doing now what patients need next