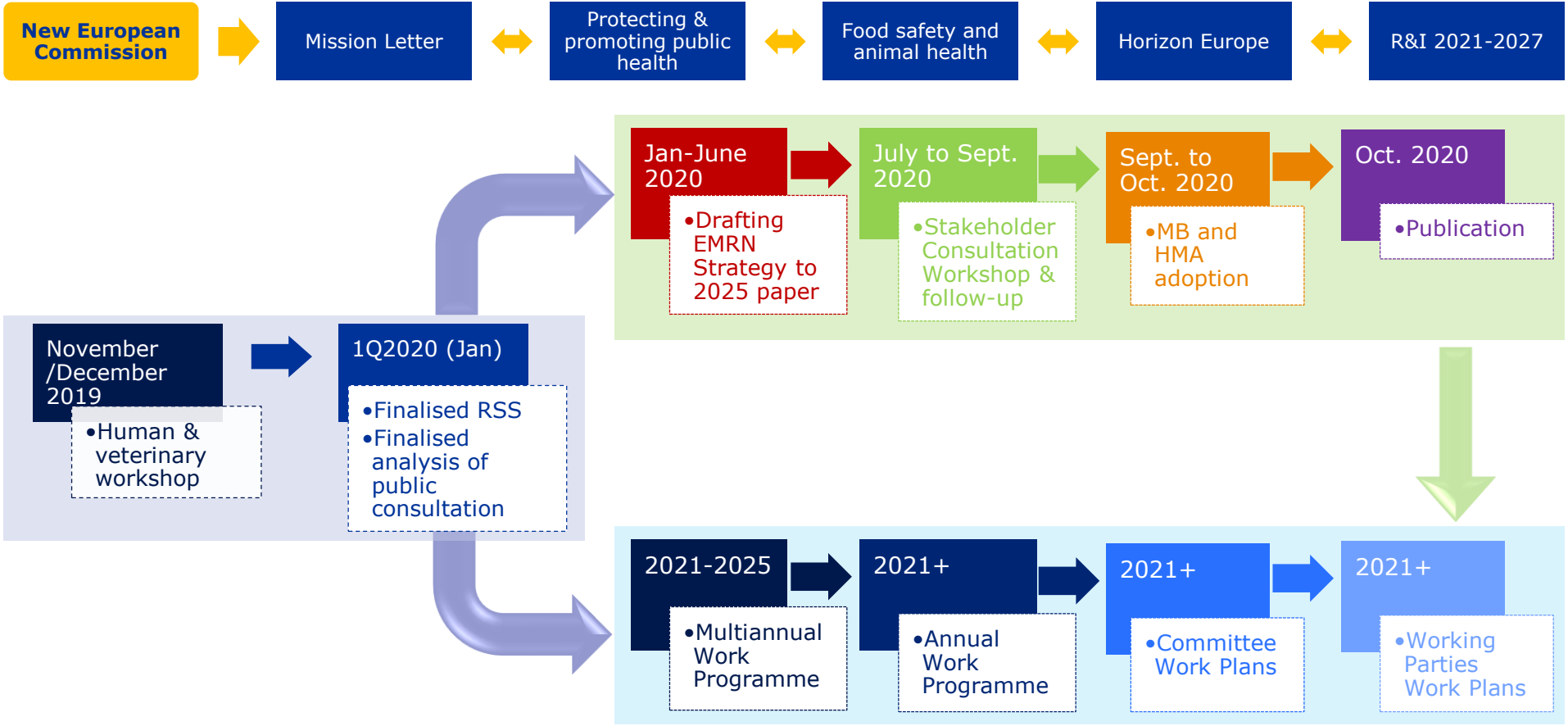
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Regulatory Science to 2025

Delivering the strategy

Veterinary Stakeholders Workshop

Presented by Guido Rasi, Executive Director, EMA on 6 December 2019



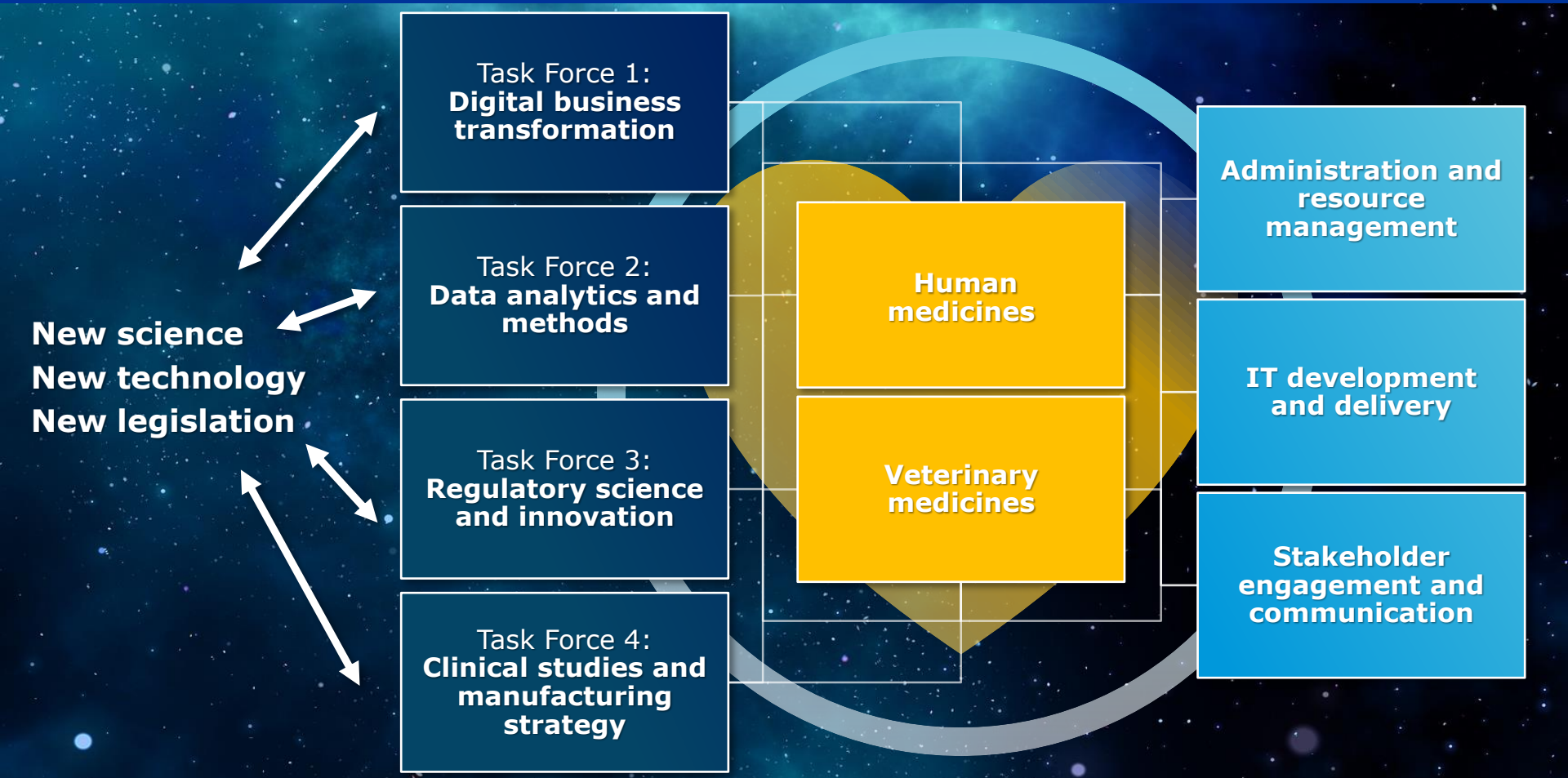
Programme management

- 5 year implementation planning
  - Recognising interdependencies
  - Prioritisation of actions
  - Identifying enablers
- Resourcing to ensure success
  - Staffing
  - Expertise
  - Budget availability
  - Training

Need new approach

Demand to do more with restrictive budget pressures

Global Standards of Regulatory Excellence rising



Refocused Regulatory Management System

Strategy
- EC Mission letter
- EMRN 2025
- Regulatory Science 2025
- Telematics strategy

Future Proof Operations
- Core processes and systems
- IT and informatics
- Infrastructure and footprints

Organisation and culture
- Organisation structure
- Governance and decision-making
- Performance management
- Talent development

Effective regulatory activities

Development
- Scientific advice
- Standards and guidance

Marketing authorisation
- Product evaluation and authorisation
- Inspections

Post-marketing
- Safety surveillance

Health impact

Increased access to innovative medicines/improved health outcomes
- Prevention of illnesses and diseases,
- Foster environment for innovation and translation

Contribute to evolving healthcare systems
- Public confidence in regulated products,

Engagement

Done

- RSS consultative process
- EMRN leadership
- Outreach
- Stakeholders consultation exercise (veterinarians, learned societies, academia, industry, HTA/payers etc.)

Yet to do

- **Need** for continued **stakeholders engagement** in delivering actionable areas
- Need **collaboration** to deliver:
  - **EC/EP/NCAs**
  - **Payers**
  - **Medical Device Authorities**
- Need to **leverage** NCAs and International Regulators' **regulatory science** programmes

Any questions?

Further information

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