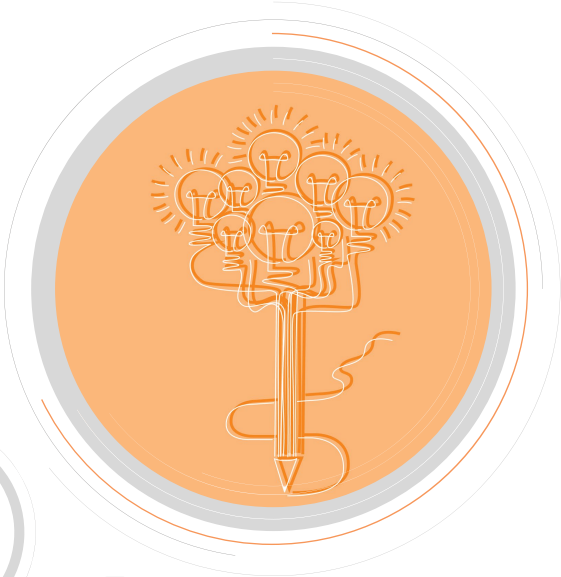
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



EMA Regulatory Science to 2025

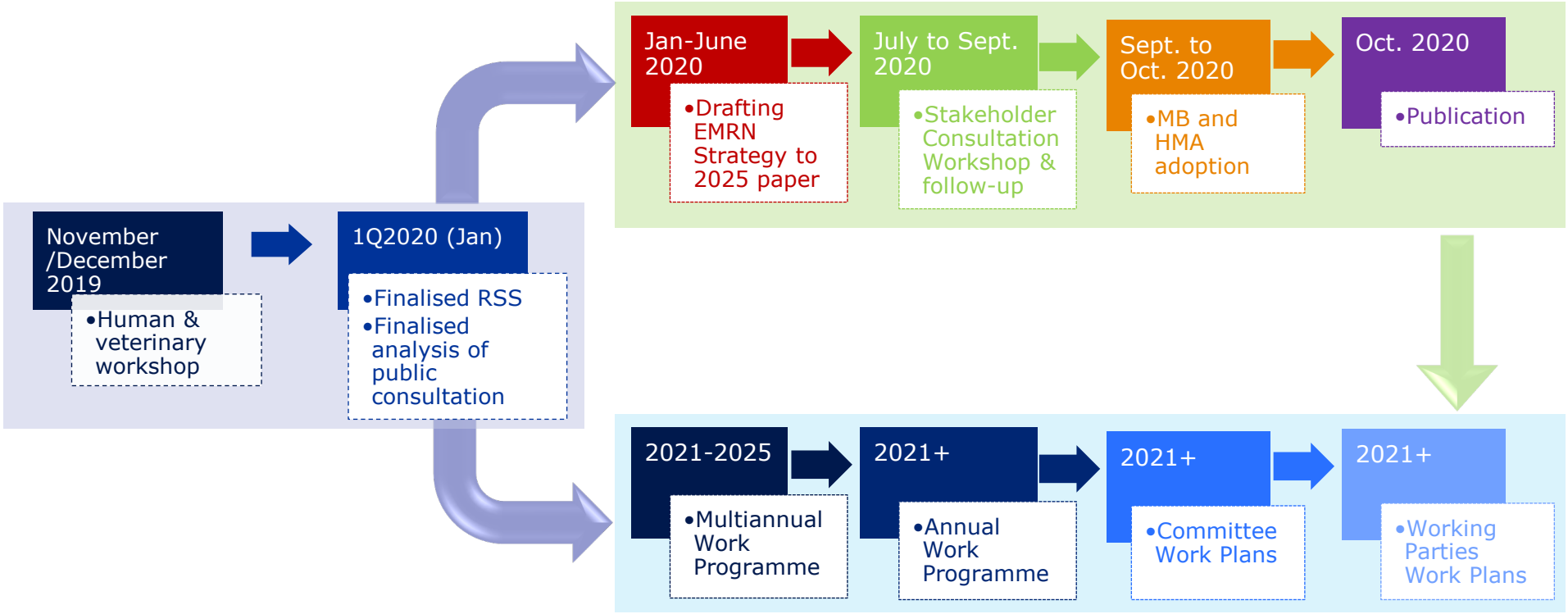
Delivering the strategy

Human Stakeholders Workshop

Presented by Guido Rasi, Executive Director, EMA on 19 November 2019

An agency of the European Union

New European Commission → Mission Letter ↔ Protecting & promoting public health ↔ Food safety and animal health ↔ Horizon Europe ↔ R&I 2021-2027



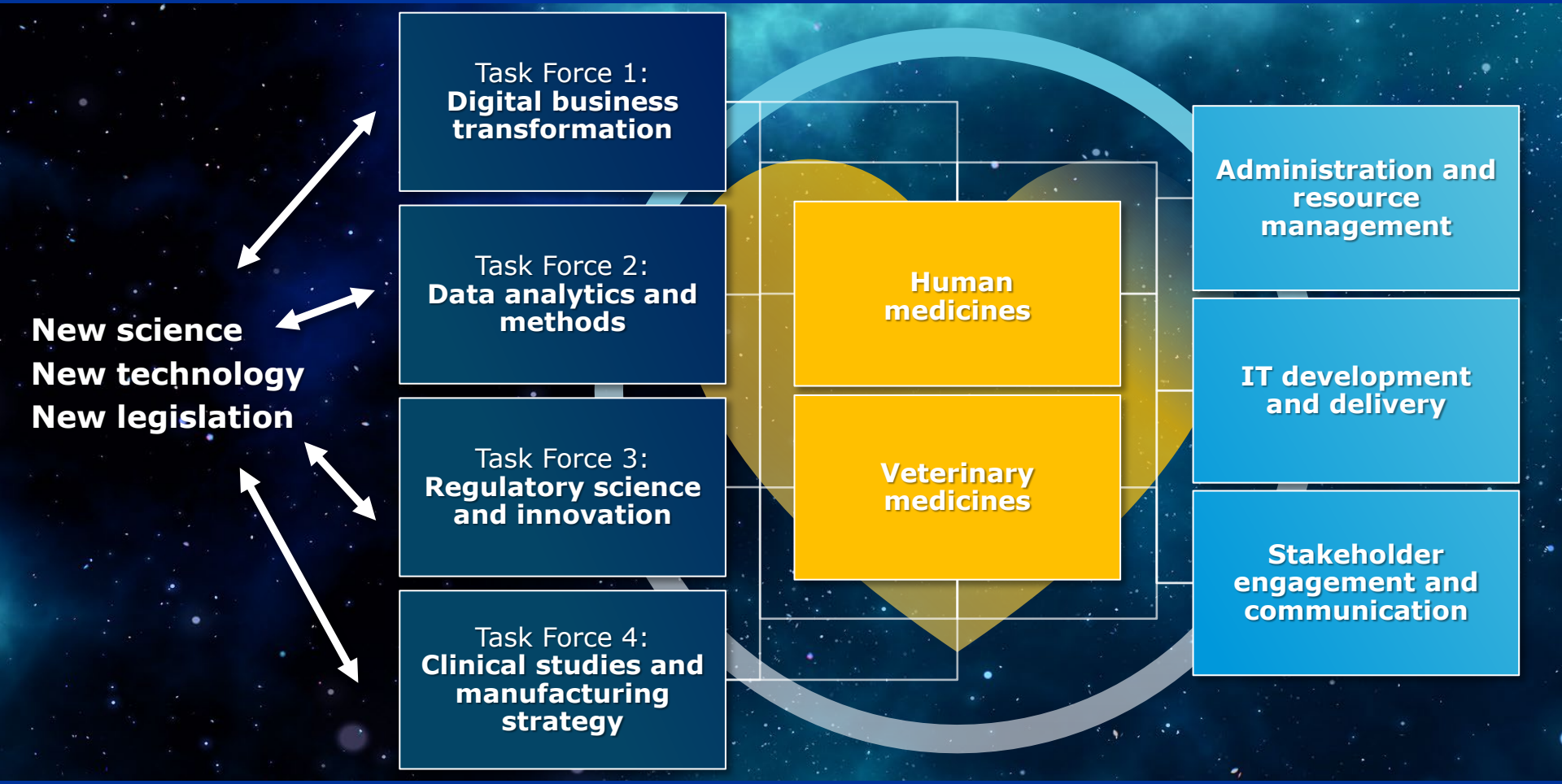
Programme management

- 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


New science
New technology
New legislation
Task Force 1: Digital business transformation
Task Force 2: Data analytics and methods
Task Force 3: Regulatory science and innovation
Task Force 4: Clinical studies and manufacturing strategy
Human medicines
Veterinary medicines
Administration and resource management
IT development and delivery
Stakeholder engagement and communication

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 / Orphan designation/ Paediatrics
- Standards and guidance

Marketing authorisation
- Product evaluation and authorisation
- Inspections

Post-marketing
- Safety surveillance

Public health impact

Increased public access to innovative medicines/improved health outcomes
- Prevention of illnesses and diseases,
- Improved quality of life

Contribute to evolving healthcare systems
- Public confidence in regulated products,
- Foster environment for innovation and translation

Engagement

Done

- RSS consultative process
- EMRN leadership
- Outreach
- Stakeholders consultation exercise (patients, healthcare professionals, 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**
  - **HTA/Payers**
  - **Medical Device Authorities**
- Need to **leverage** NCAs and International Regulators' **regulatory science** programmes

Any questions?

Further information

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