



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR Workshop (defining a business case for the EU network)

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An agency of the European Union





The business case

- Definition:
 - An analysis of the organisational value, feasibility, costs, benefits and risks of a project plan
- Attributes of a good business case:
 - Details of the possible benefits, risks and complexity to the different stakeholders
 - Clearly compares alternatives
 - Systematic in terms of summarising findings

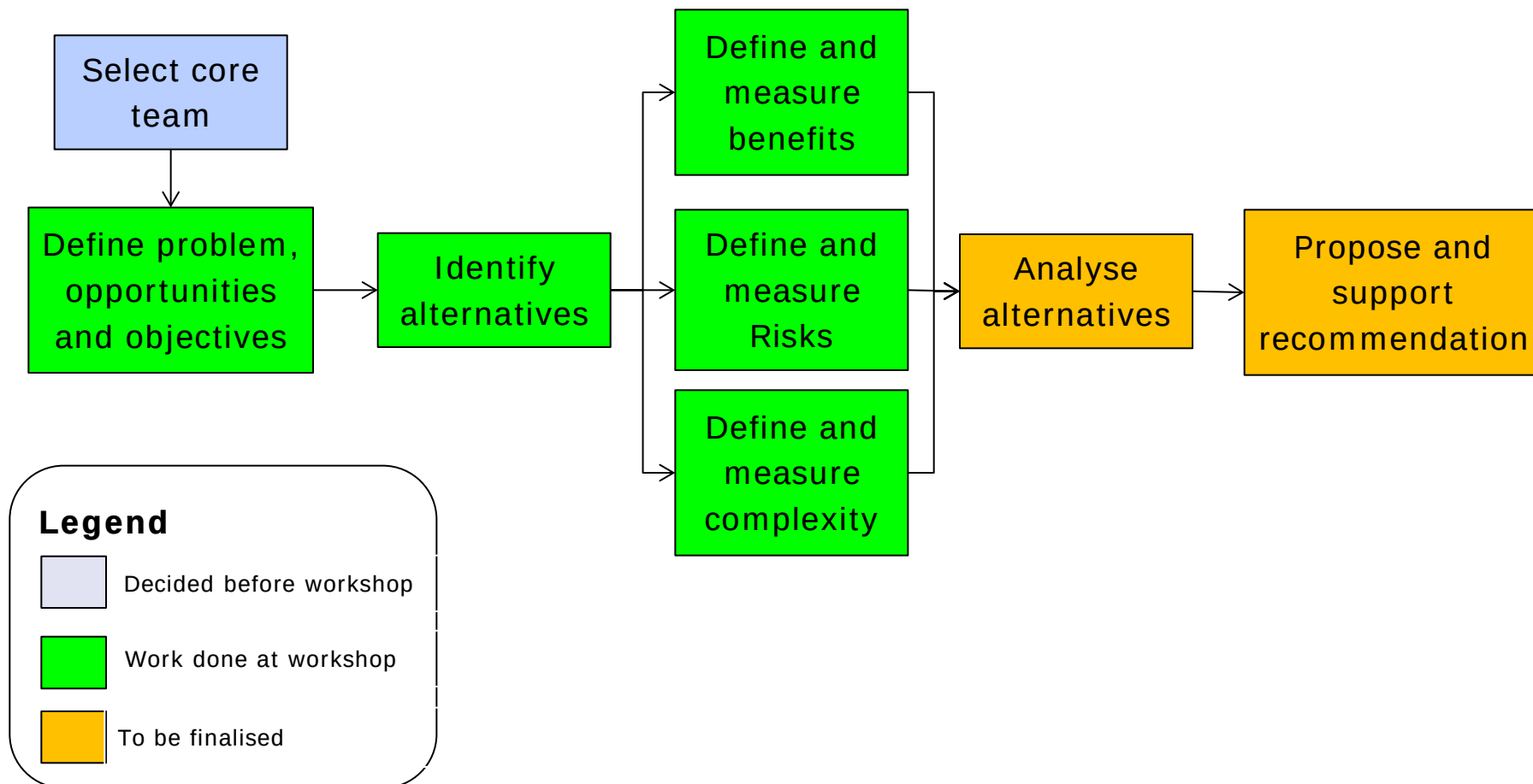


Questions to be answered during the workshop

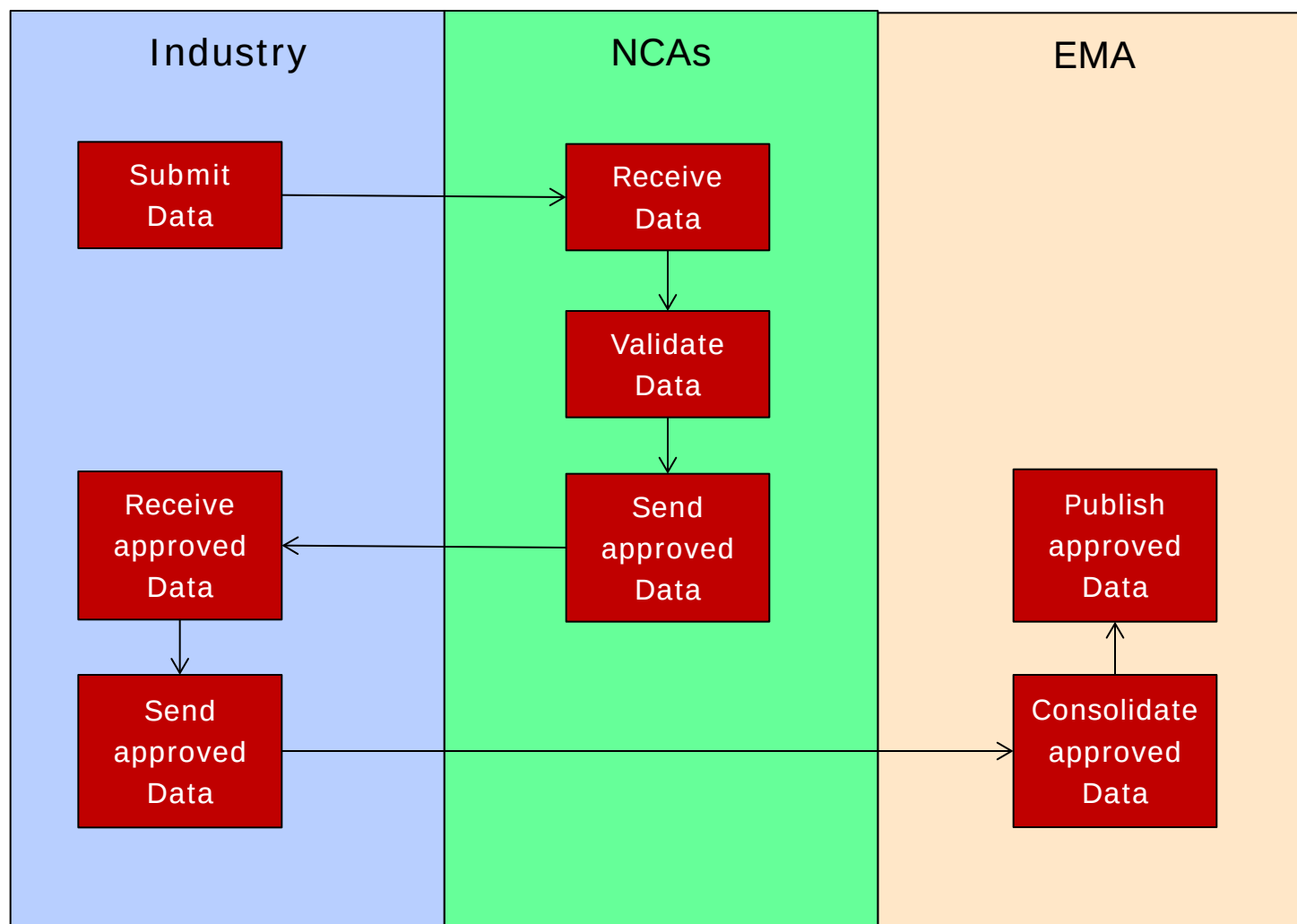
- Why (problem/opportunity and objectives)?
- Where (scope: i.e. Human and Veterinary, SPOR)?
- What (options, operating model, benefits, risks, complexity)?
- Who (ownership, role and responsibility)?
- When (roadmap)?
- How (managing change, communication, support)?



Process for developing the business case



Alternatives (dummy example)





Benefits

Drivers	Objective	Comment
Effectiveness ¹	Decision making	Better decision making due to better DQ and integrated lifecycle of product
Efficiency ²	Reduce data management	eAF: reduce number of manual tasks 1) re-enter master data 2) validate master data, etc
IT (agility)	Reduce integration costs	Reduce requirement to integrate/publish master data across systems
Compliance	Privacy/security	Single customer/patient view across silos leading to reduce risk exposure
	Legislation	Ability to meet the IDMP legislative requirement

1. Effectiveness = capability of producing a desired result

2. Efficiency = extent to which time, effort, or cost is well-used for the intended task or function



Complexity/risks

Drivers	Challenge	Comment
Financial (incl. resources)	Extra resources required with specific skills	Time is required to employ and train new resources
Business (organisational)	Change management	Need for training organised by XXX
IT (easy of implementing)	Need to modify existing systems	A project is required to change existing systems
Compliance	Delays in legislation	Acceptance from EC and network on new implementation deadlines.



Benefits marking scheme

Score	Definition
5	Excellent: very high expectation for significant improvement in efficiency or quality
4	Good: moderate expectation for improvement in efficiency or quality
3	Acceptable: benefits expected to be balanced with costs for implementation
2	Low: significant risk of benefits not being achievable due to cost or complexity
1	Poor: benefits are hard to identify or not expected to be of sufficient value to stakeholders



Complexity/risks marking scheme

Score	Definition
5	Critical: complexity/risk will have a serious effect on performance or reputation in the long term (permanent)
4	Major: complexity/risk will have a serious effect on performance or reputation in the medium term (3 to 12 months)
3	Moderate: complexity/risk will have a significant effect on performance or reputation in the short term (less than 3 months)
2	Minor: complexity/risk is unlikely to have any permanent or significant effect on performance or reputation
1	Negligible: minimal complexity/risks



Benefits (marking scheme 1 to 5) - example

	Option 1	Option 2	Option 3
Effectiveness	3	1	2
Efficiency	3	4	3
IT (agility)	5	3	4
Compliance (legal, security, privacy)	4	2	2
Total Score	15	10	11



Complexity/risks (marking scheme 1 to 5) - example

	Option 1	Option 2	Option 3
Financial (resources)	2	3	4
Business (organisational)	2	4	4
IT (easy of implementing)	4	4	3
Compliance (legal, security, Privacy)	4	2	5
Total Score	12	13	16

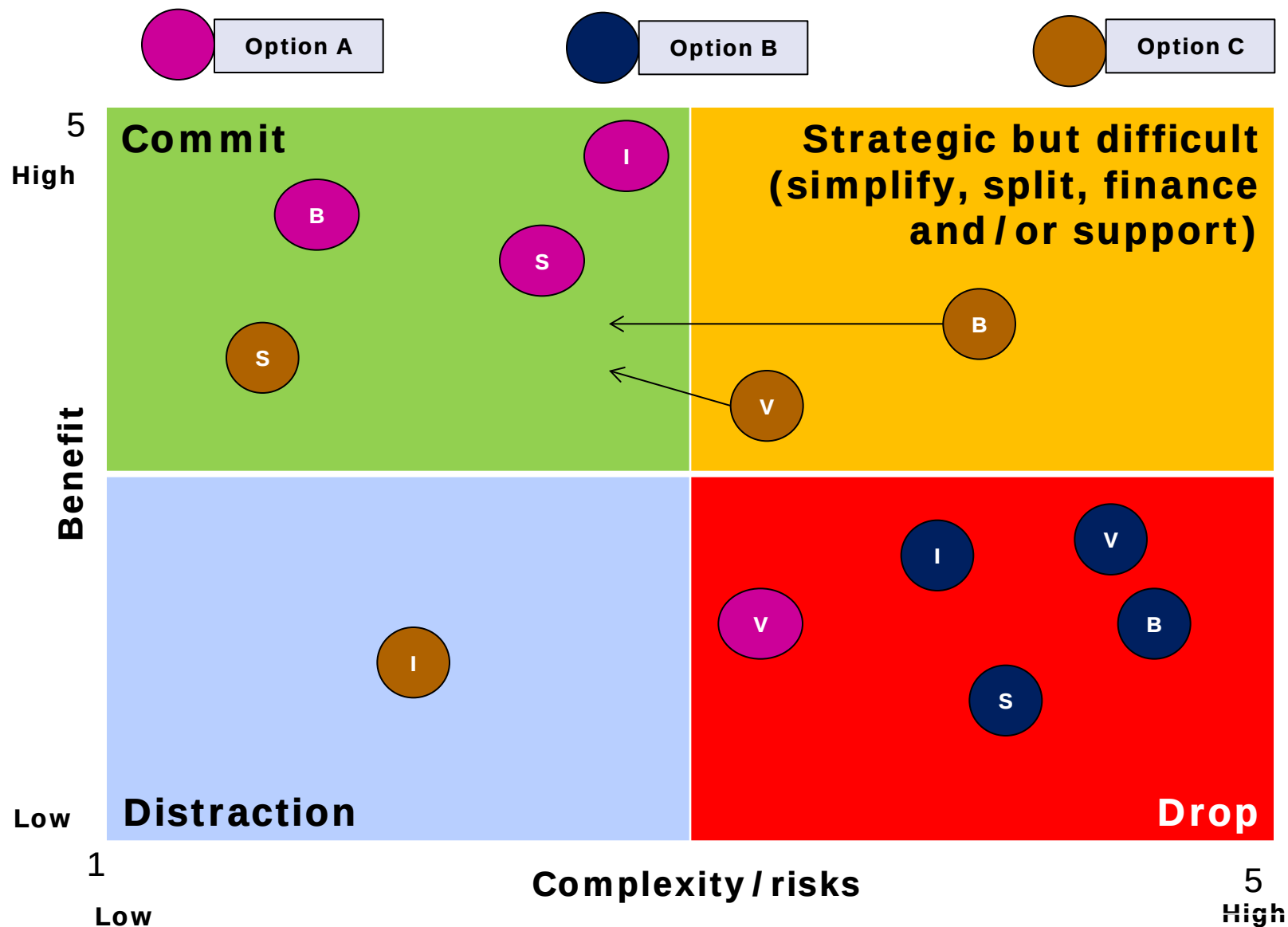


Benefits (marking scheme 1 to 5 - normalise)

	Large& Medium NCAs	Small NCAs	Vet NCAs	Industry
Option A	4	3	3	3
Option B	5	2	2	3
Option C	2	3	3	2

Complexity/risks (marking scheme 1 to 5)

	Large& Medium NCAs	Small NCAs	Vet NCAs	Industry
Option A	3	4	2	3
Option B	2	2	5	1
Option C	4	1	1	4





Next steps

1. Discussion at the EU Network Data Board
 - Propose NCA/EMA recommendation
2. Discussion at the EU ISO IDMP TF
 - Propose Industry/NCA/EMA recommendation
3. Discussion at EU level with all NCAs
 - Adoption of the final recommendation



QUESTIONS

