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Evaluating "immature" technologies: grading uncertainty and informing the Coverage with Evidence Development Option

The case of the da Vinci Robot

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Evaluating Immature Technologies: The da Vinci Robot project (2007)

Objective

- clinical indications for which <u>at the moment</u> the technology would not offer considerable advantages

- clinical indication for which the technology seems to offer considerable advantages

  - monitoring of scientific literature
  - research programmes

The “Coverage with Evidence Development” option

How to balance

Cost of waiting for better information

Cost of premature diffusion

Delay / denial of effective care

Spread of ineffective / harmful care

Withdrawing a service is more difficult than witholding it

When should CED be used ?

- **Does current evidence suggest that the innovation is better than current practice ?**
- **Is collection of more information worthwhile ?**
- **Should we wait for more information ?**

is suggested that CED is best suited to the following circumstances: where there are reasonable grounds for believing that a technology will offer significant benefits but there is uncertainty around the clinical or cost-effectiveness of the technology that can be overcome through evidence that can be generated in an appropriate time frame, and is the main source of equivocality in a coverage decision.

International Journal of Technology Assessment in Health Care, 23:4 (2007), 425–435.

A powerful tool for
Evidence-Based Decision Making

Evaluating Immature Technologies

- The questions:
  - Is it going to be effective ?
  - Is the context appropriate ?
  - Is it going to be economically sustainable ?
- The information:
  - Research results
  - Context's attributes
  - Economic analyses
- The tools to interpret / use the information:
  - Index of trialability
  - Index of context's adequacy
  - Index of sustainability

Evaluating Immature Technologies

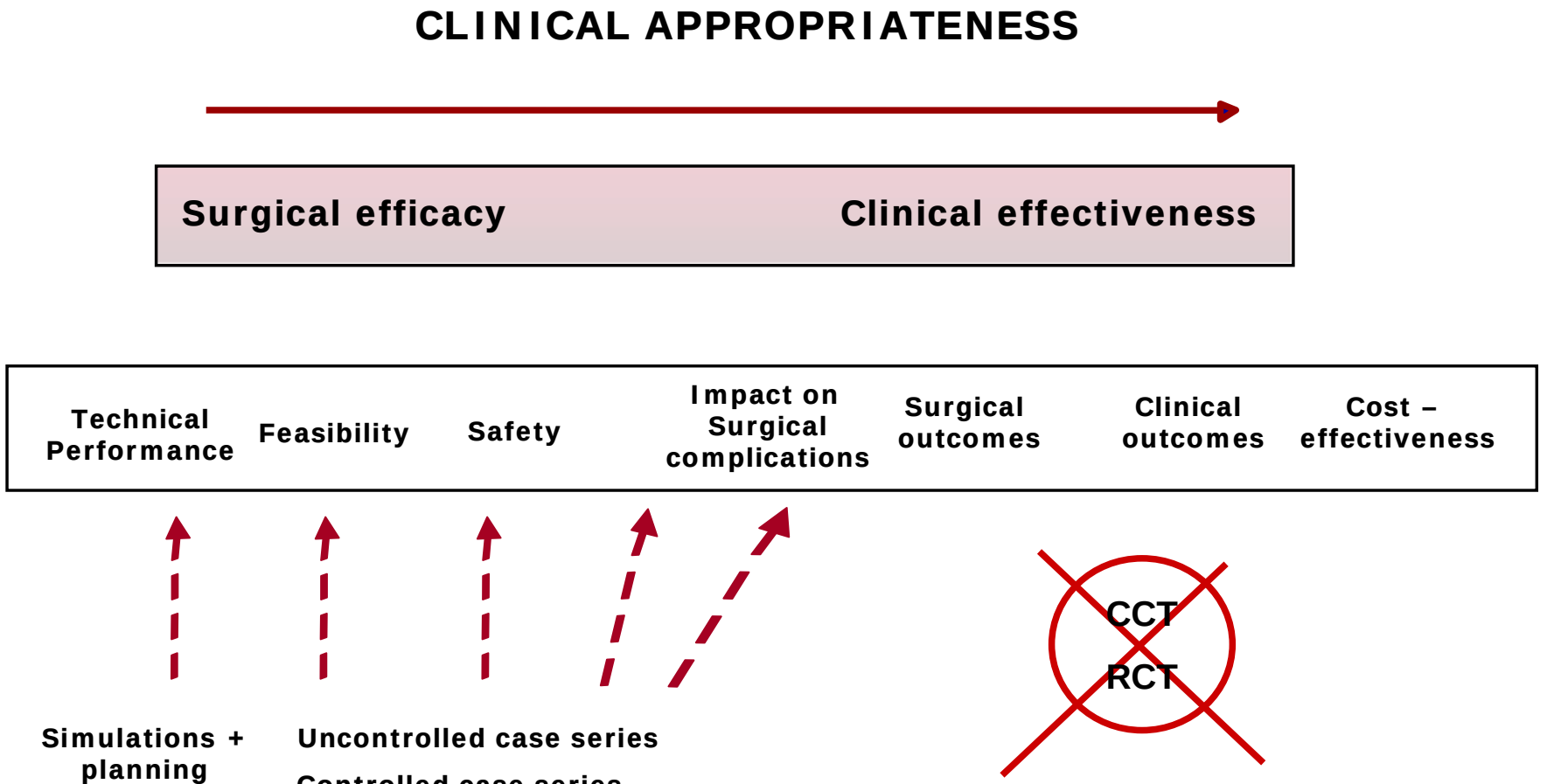
- the *rationale* of the technology
- the dimensions to be evaluated
- the relevant outcomes for each dimension
- the appropriate comparator
- the appropriate study design for each outcome

"EVIDENCE PROFILE"

Dimension	Outcome		Study design
Clinical effectiveness	<u>Primary outcomes</u> Remission, recurrence, survival		RCT CCT
	<u>Secondary outcomes</u> Functional Post-operative complications Quality of life		RCT CCT Controlled case series
	<u>Surgical outcomes</u> Radicality Adequate dissection / lymphadenectomy Adequate margins		RCT CCT Controlled case series
Safety	Peri-operative complications Blood loss Transfusions Re-intervention		RCT CCT Controlled case series Uncontrolled case series
Feasibility	Operating time Conversion to laparoscopy Conversion to open surgery	Length of Stay Learning curve / training Costs	Controlled case series Uncontrolled case series

"Evidence profile" and Review of Literature

Rationale: Conservative surgery's better performance than open or laparoscopic surgery for surgical intervention on very small fields



Immature Technologies and the synthesis of studies' results

Given that no quantitative synthesis is feasible

- What to make of results ?
- How to present results ?
- How to say something meaningful ?
- Is it possible to describe uncertainty?

Looking for a way to "grade" uncertainty

The risk of non-effectiveness

The information: results from literature review

FEASIBILITY → SAFETY → EFFECTIVENESS → COST-EFFECTIVENESS

Classifying uncertainty

Steady results

results that are highly unlikely to be changed by further studies

Plausibly stable results

consistent results, coming from sufficiently numerous observational studies, which would probably not change significantly if evaluated through randomised clinical trials

Uncertain results

results that would most probably change, in both size and direction of estimate, if evaluated through randomised clinical trials

Unknown results

unreported or non-existent results on outcomes judged by the panel to be relevant for the evaluation of the technology

Synthesis of literature review's results

Gastrectomy (2 case series on 7 e 9 patients respectively)

FEASIBILITY	SAFETY	SURGICAL OUTCOMES	SECONDARY CLINICAL OUTCOMES	PRIMARY CLINICAL OUTCOMES
costs	intra-operative complications	Positive margins	Time to nutrition	Disease free survival
conversion to open/laparoscopic surgery	post-operative complications.	Adequate lymphadenectomy	Weight loss	recurrence
Operating time	blood-loss /transfusion	Adequate dissection		Overall survival
Learning curve	re-intervention			

Radical Prostatectomy (2 HTA, 8 systematic reviews of case series, 4 case series)

FEASIBILITY	SAFETY	SURGICAL OUTCOMES	SECONDARY CLINICAL OUTCOMES	PRIMARY CLINICAL OUTCOMES
costs	intra-operative complications	Positive margins	Continence	Biochemical failure
conversion to open/laparoscopic surgery	post-operative complications.		Sexual potency	Recurrence
Operating time	blood-loss /transfusion			Survival
Learning curve	re-intervention			

Steady results

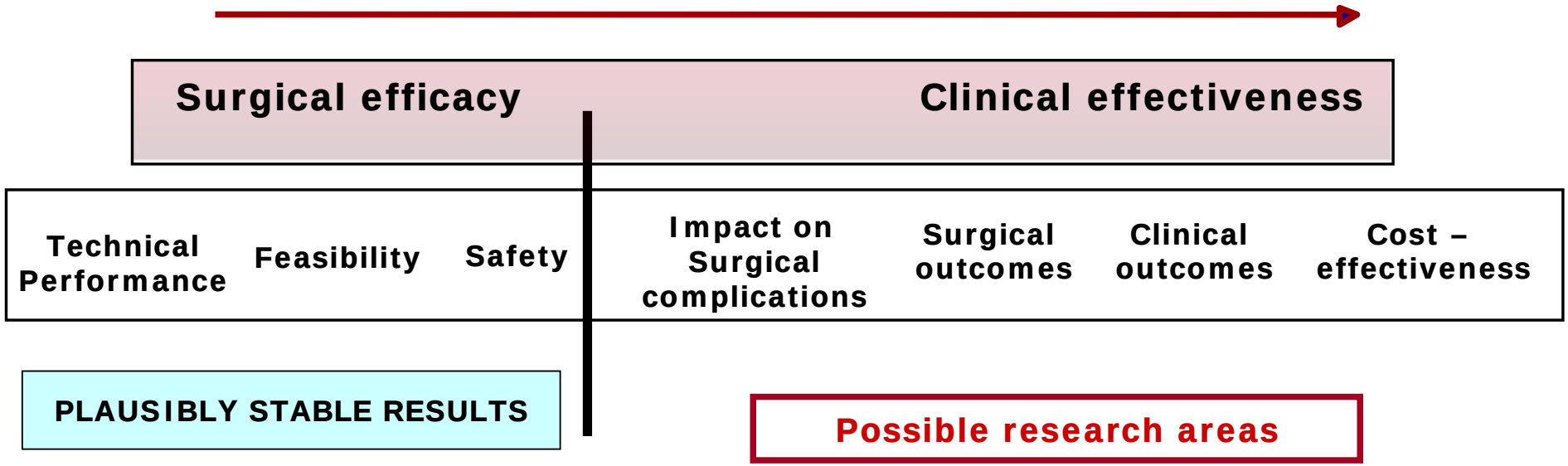
Plausibly stable results

Uncertain results

Unknown results

Robotic surgery: results

CLINICAL APPROPRIATENESS



PLAUSIBLY STABLE RESULTS

Exclusion based on trialability index:

Thoracic Surgery
Gastrectomy

Exclusion based on relevance of outcomes:

Cholicistectomy
Fundoplication

Possible research areas

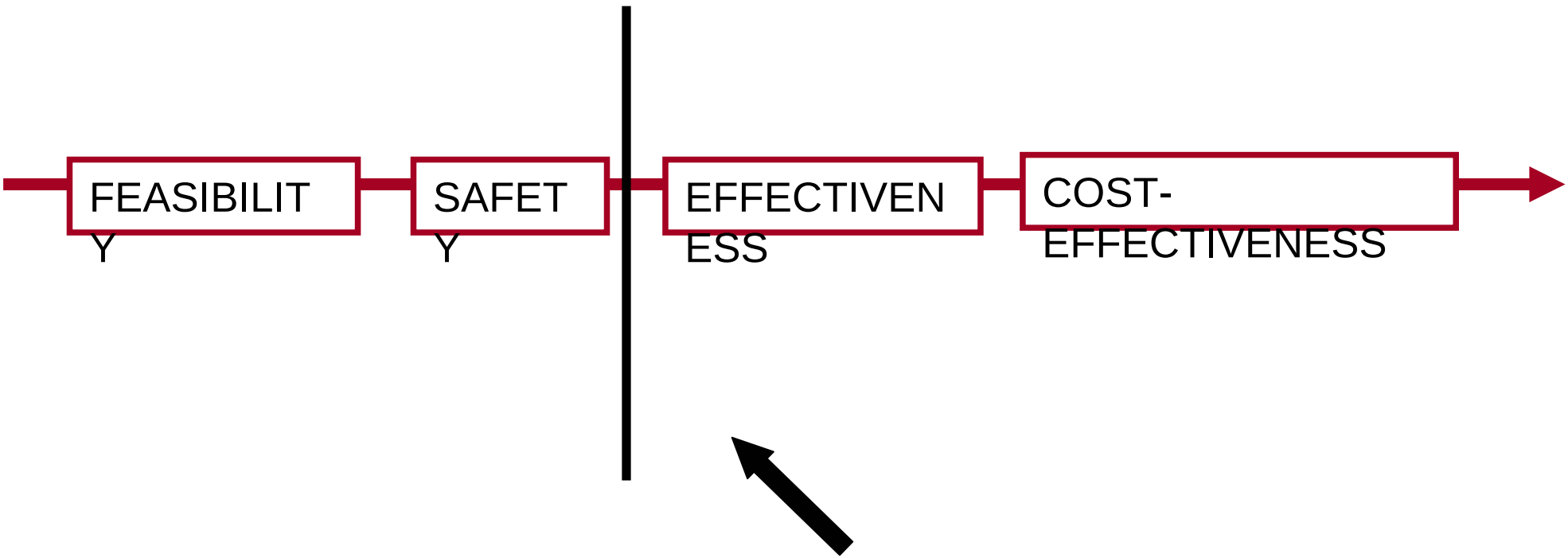
Urological surgery
Gynecological surgery
Bariatric surgery
Colon surgery
Rectal surgery

The “acceptable” uncertainty

The tool: trialability index

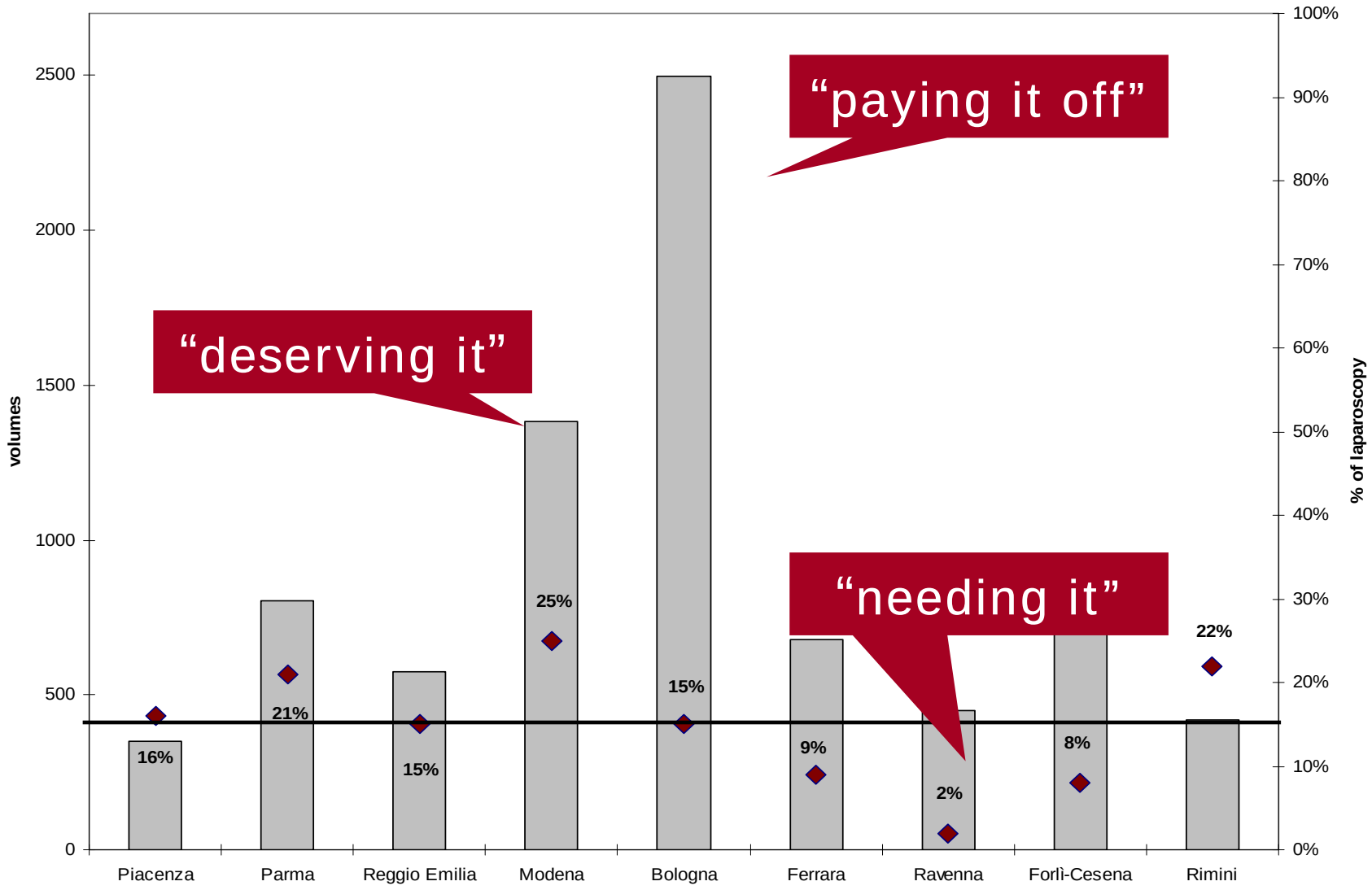
Cut-off point at which Results ≥ plausibly stable are accepted

(or from which plausibly stable results are not accepted / sufficient)



Depends on the *rationale* underpinning the technology

Is the context appropriate ?
Possible locations of the da Vinci robot:



Is it going to be sustainable?

The information: costs

Table 1: Fixed costs

Amortization	210.000,00
Maintenance	168.000,00
Rentals	0,00
Others	0,00
Total fixed costs	**378.000,00**

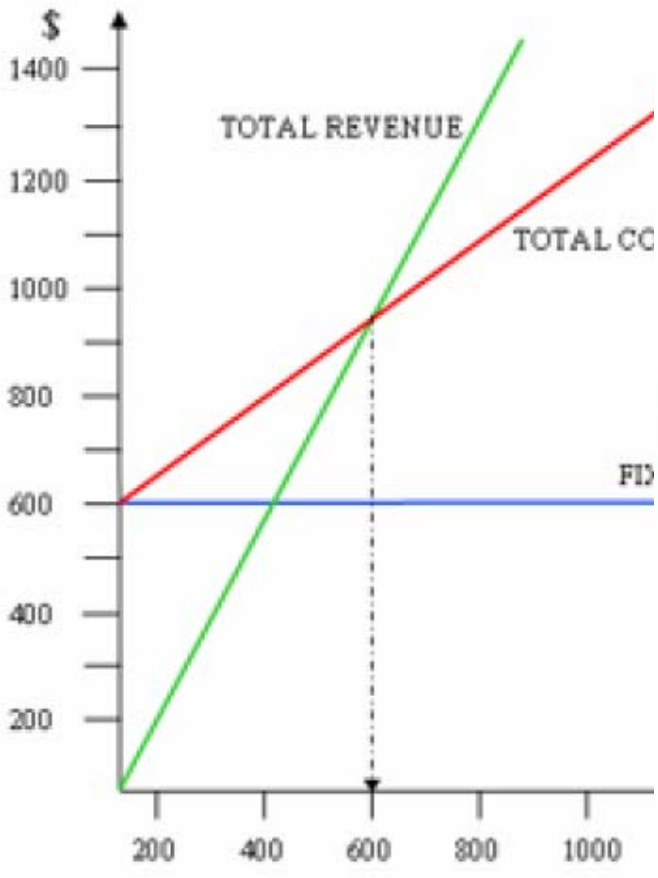
Break even point

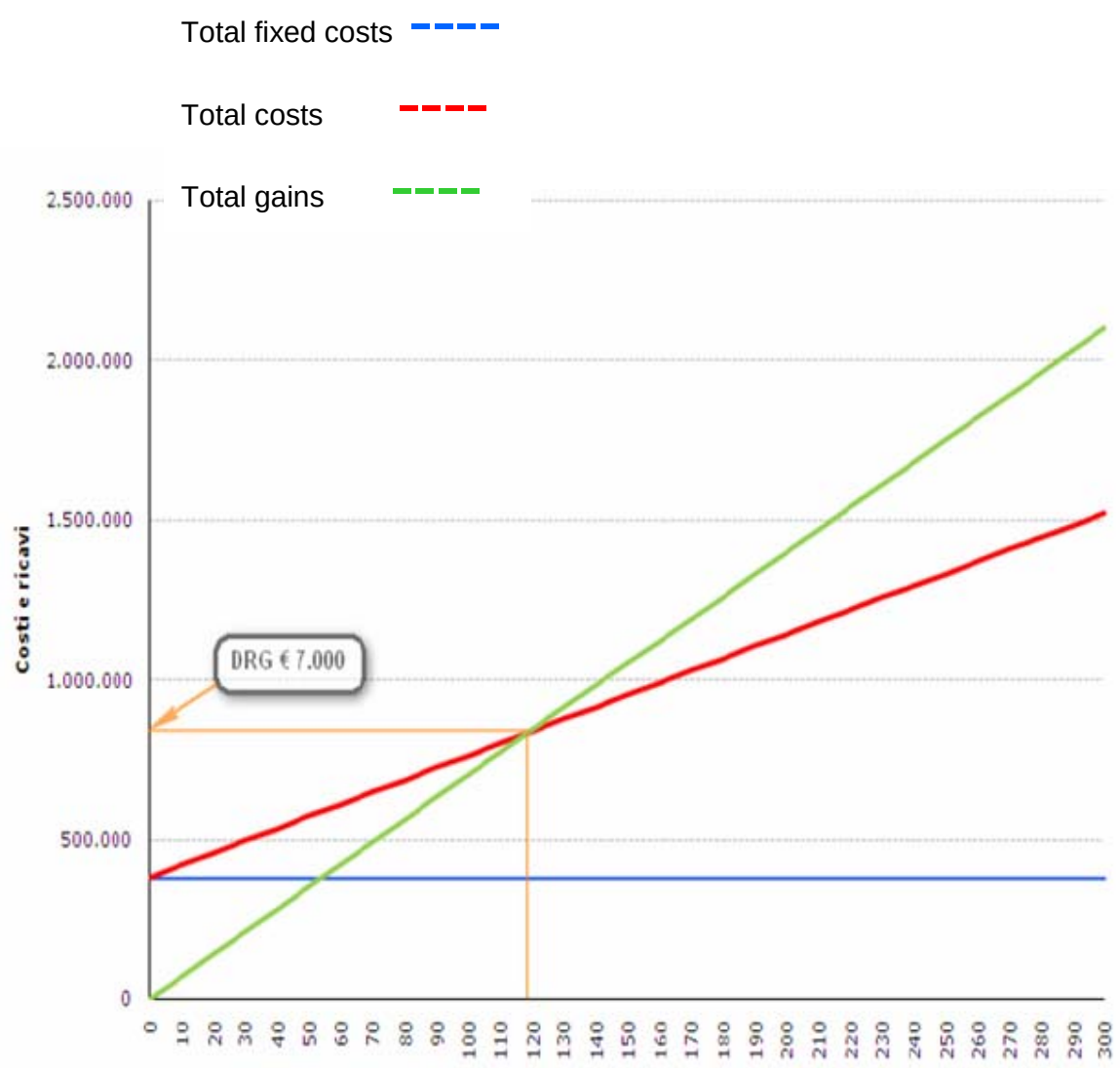
$$BEP = \frac{CF}{p - cv} = 548$$

Table 2: Variable costs

	Cost of 1 unit of production
Cost of hospital stay (2 days)	800,00
Cost of personnel	815,72
Cost of disposable	1.916,65
Intermediate clinical services costs	27,20
overheads	251,30
Total variable costs for 1 unit of production	**3.810,87**

The tool: Break Even Analysis





Da Vinci robot project: conclusions

EXCLUDED

Diffusion in clinical practice
Further acquisitions outside of approved regional programmes of training and research

Clinical use only within formal trials

Training

ACQUIRE IF :

. Economic resource available over few yrs
. Inter - dipartmental location
. Trained – expert surgeons available
. Participation to RCTs viable
. Monitoring + evaluation programmes

DISMANTLE IF :

. Under-use or mono-disciplinary use
. Trained surgeons not present
. Small volumes of activities
. Lack of infrastructure for participation to research programmes

The role of Experts

Evaluation of Immature Technologies:

definition of the potential clinical use of a technology

Experts define the evidence profile

Agree on clinically relevant outcomes

Define the research needs

Da Vinci robot project: outputs

2 multi-center controlled trials – RER

Radical Prostatectomy

< post – operative complications: continence + sexual potency

= biochemical failure, recurrence

Colectomy

< post – operative complications: conversions to open / laparoscopic

= recurrence

Thank you

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PROCESS FOR THE EVALUATION OF AN EMERGING TECHNOLOGY

Step	Process	Output
Step 1	–Technical description of the technology –Definition of relevant outcomes –Systematic review of literature	–List of clinical outcomes ranked by level of importance –Full systematic review of all published literature on selected clinical indications
Step 2	–Quantity and quality of published research results by clinical indication for each outcome	–*Evidence mapping*
Step 3	–Definition of exclusion criteria: a)cut off-line above which level of uncertainty is considered too high to carry out research programmes; b)outcomes considered of insufficient clinical value	–List of excluded clinical applications
Step 4	–Data report on volumes of activity and size of potential population target –Distribution of organisational excellence and professional expertise	–*Context mapping*
Step 5		–Clinical indications for research

Identify relevant research questions

Evidence mapping allows to exclude clinical indications on the basis of explicit criteria:

- **Clinical criteria**
  - **The cut-off line for "acceptable uncertainty"**
  - **The relevance of the clinical outcomes**
- **Criteria related to context**
  - **Data on population targets + volumes of activity**
  - **Areas of clinical + research excellence**