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Abt Bio-Pharma Solutions

REAL WORLD. REAL VALUE.

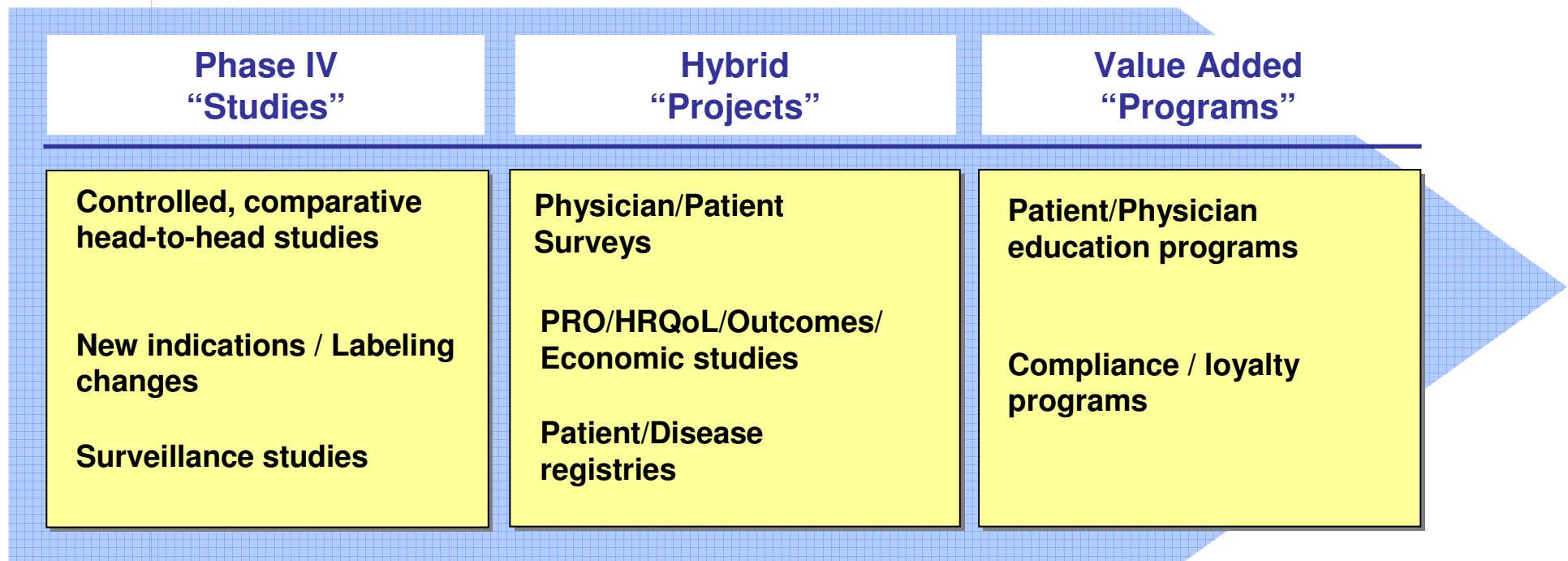
**Breakout Session 1:
Post-Marketing Programs –
a (mostly) European Perspective**

Basel, May 5, 2008

Post-Marketing Program Characteristics:

- Following a product's introduction into the marketplace (Phase IV) – initiation can take place before launch
- In the real-life setting of day-to-day routine clinical practice
- In larger and heterogeneous patient populations
- Data assessments commonly follow routine practice, i.e. no prescribed interventions, reduced burden on physicians and patients (study drugs generally not financed by sponsor)
- Overall study procedures tend to be less rigorous than in clinical research (non GCP compliant). *Exceptions:* patient consent, data confidentiality, adverse event reporting
- Audiences for post-marketing real-life data include all the major players in healthcare: physicians, patients, payers and regulatory as well as pricing/reimbursement authorities

The Marketing Program „Continuum“

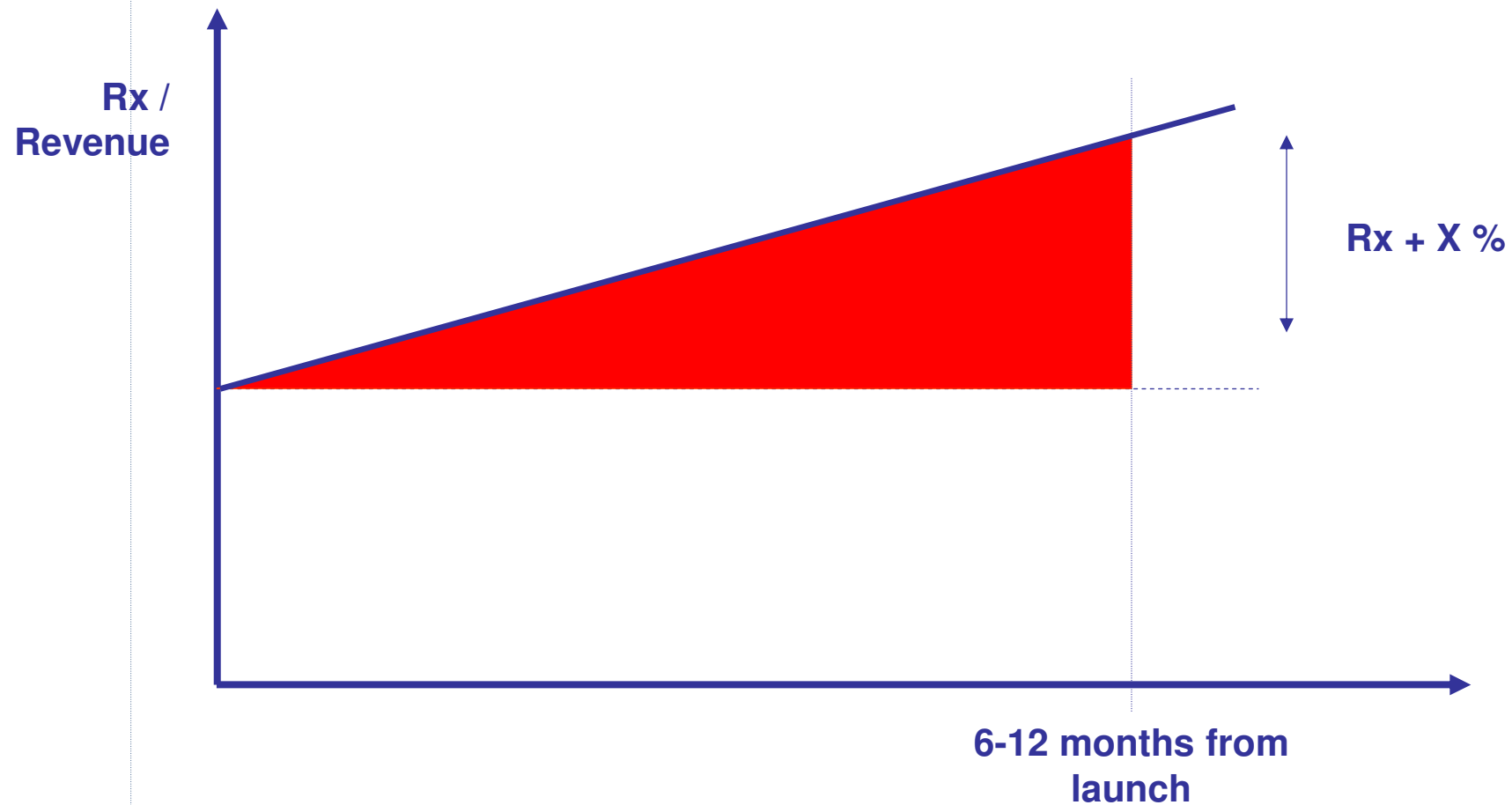


- Where you position your study depends on your diverse strategic objectives

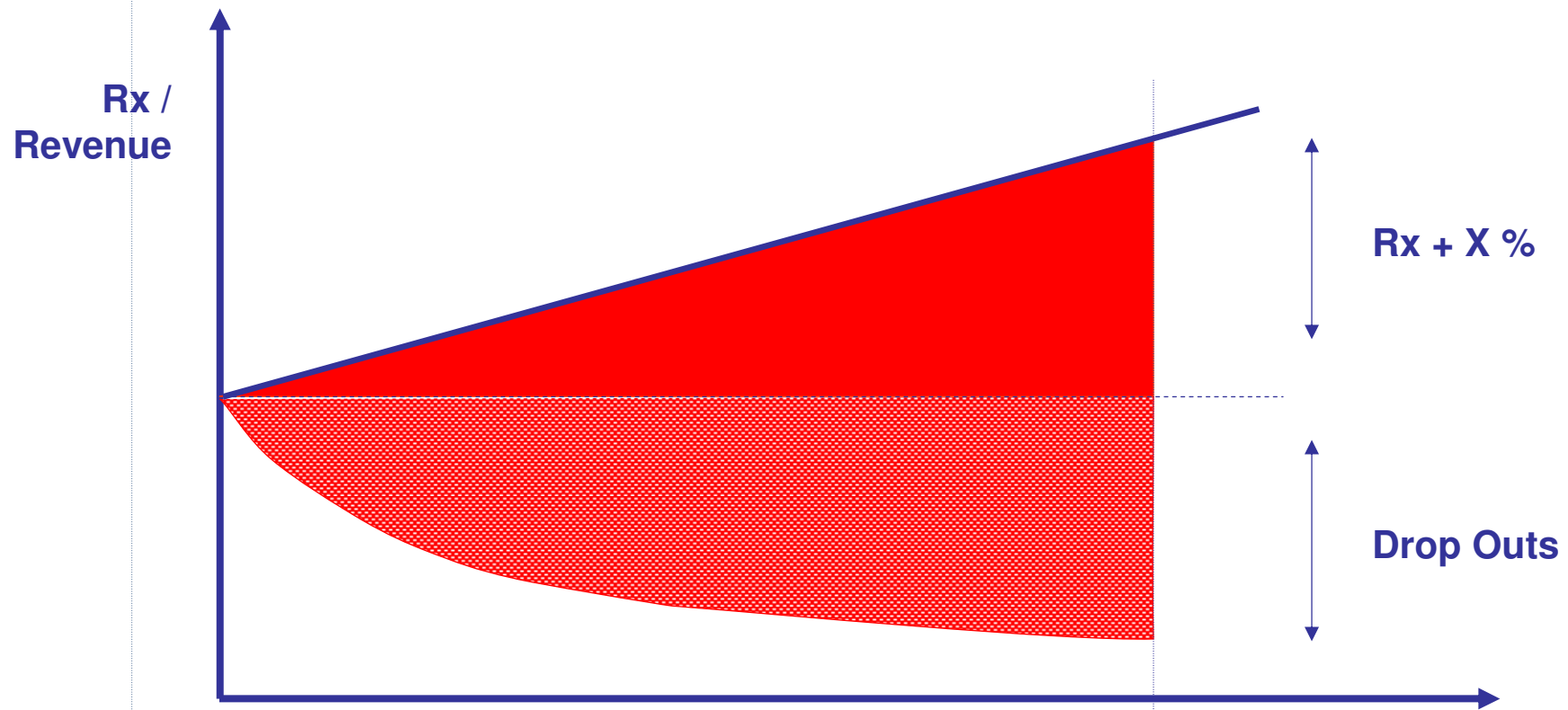
Data from Post-Marketing Programs are typically used to:

- Convince regulatory authorities that the product is safe in broad, heterogeneous patient populations
- Convince physicians of the product's effectiveness and value in clinical practice, in their own patients
- Expand and prepare the marketplace and support a new compound's launch
- Convince patients of the product's benefits for them personally and to use the product appropriately and regularly (compliance), to achieve an optimum of therapeutic benefit and tolerability
- Obtain and maintain reimbursement, both in terms of the reimbursed indication(s), the market price, and – in the longer term – to defend against the erosion of price and reimbursement

Business-Objectives \Rightarrow Rx Growth, increase in market share, minimal time to peak sales.....



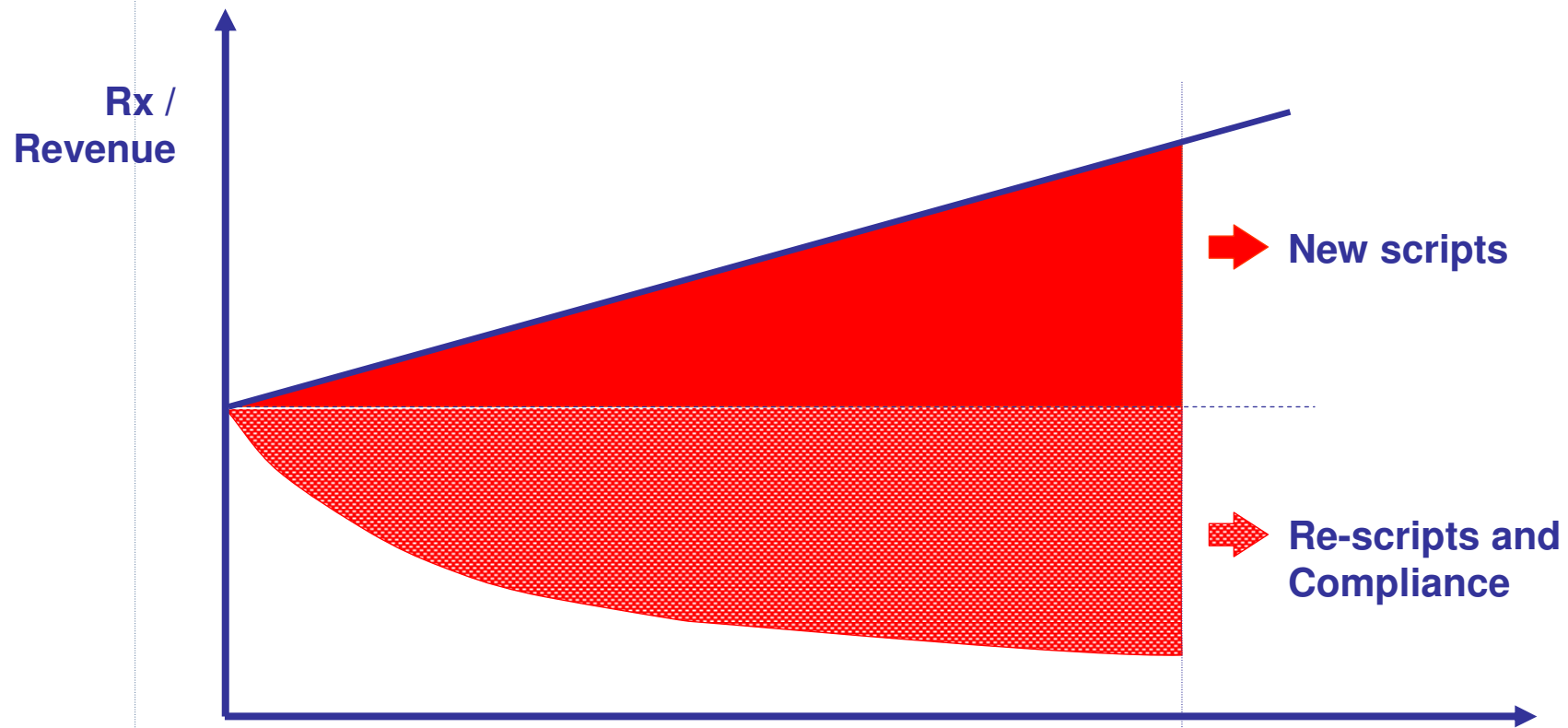
Dilemma \Rightarrow Drop Outs



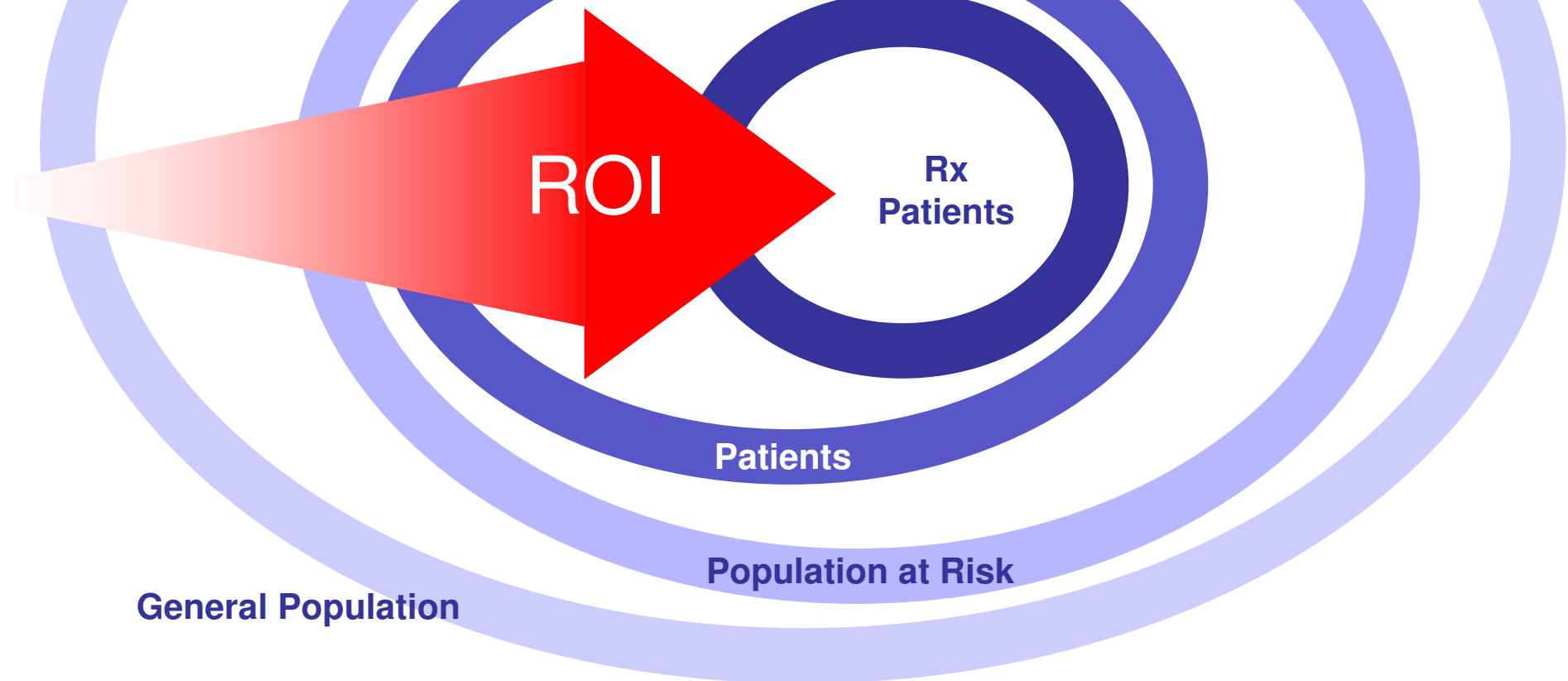
Source: I. Arnet et al, Kantonsspital Basel.

„Überzeugung als Fundament der Compliance und Techniken zur Compliance Optimierung.“ Schweiz Med Wochenschrift 1999; 129:1477-86 Peer reviewed article

Business Objectives of Post-Marketing Programs

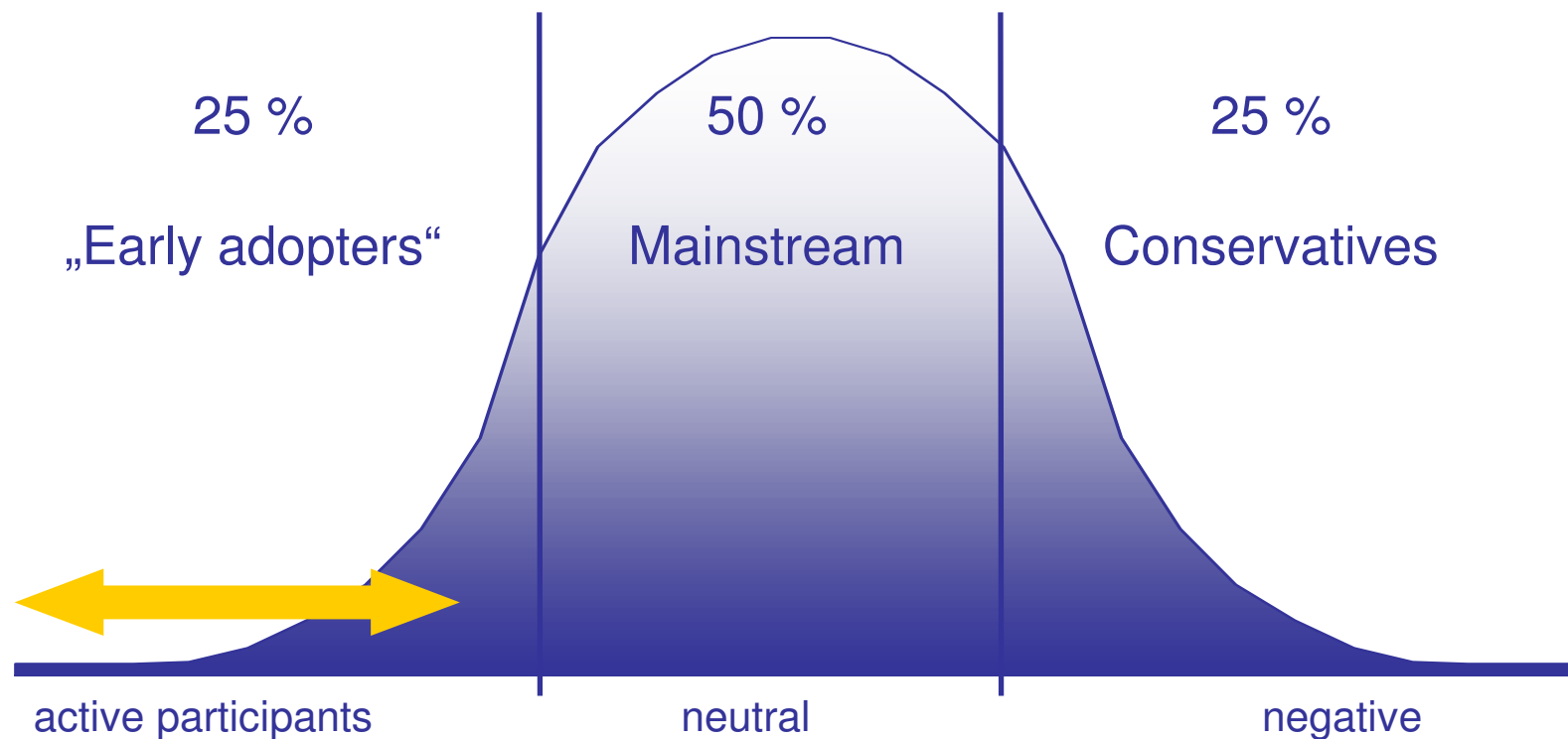


Post Marketing Program Return on Investment: one Key to „selling“ Programs Internally



- Identifying and recruiting the right patients

Physician Participation in Post Marketing Programs



➤ Identifying and recruiting the right physicians

Proposed Case Studies

- Expanding the US Osteoporosis Market - *N.O.R.A.*
- Launch of an innovative compound in Pulmonary Arterial Hypertension (PAH) - *The PAH Online Registry*
- Satisfying EMEA risk mapping and safety monitoring demands - *The PAH Online Registry*
- Building a European Franchise in Multiple Sclerosis - *MyMSLine*
- Maintaining reimbursement by demonstrating optimal on-label use of a novel metabolism compound – *a pan-European drug utilization Registry*
- A (failed) attempt to corner the Cox2 market in Germany – *a PRO survey program*
- **Optionally: additional case studies or challenges presented by members of the group**