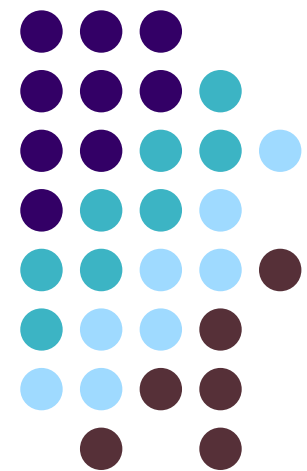


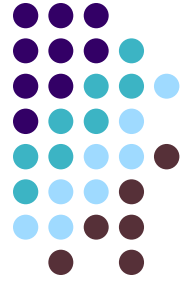
Managing the Risks of Marketing Nanotechnology Medical Products

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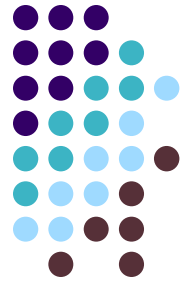


Is nanotechnology different?



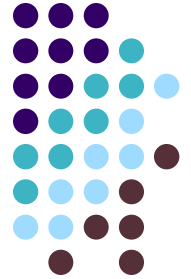
- Yes AND No
- Science
- Regulation
 - Development
 - Marketing
 - Post-marketing safety
- Business

WHAT is nanotechnology risk management?



- Product-centric
 - More than insurance and less than enterprise risk management
- Identifying and managing all major business risks in developing and marketing a prescription product
 - Emphasize product safety, litigation avoidance
- Continuous review--“life cycle risk management”

WHY nanotechnology risk management?



- Corporate focus on patient protection
 - Proactive not just reactive
 - Limits of clinical trials
 - Limits of spontaneous reports
- Avoid after-the-fact surprises from marketing of first-in-class products, based on new technology, for use in chronically ill populations

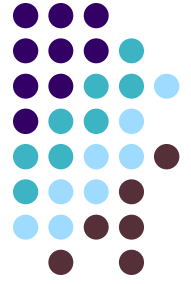


WHY nanotechnology risk management?



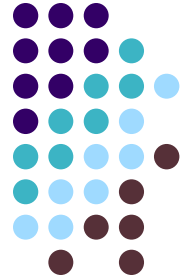
- Avoid significant external threats to the product and the business
- Major litigation and recalls pose the greatest external risks
 - Personal injury tort actions (negligence, strict liability)
 - Consumer fraud class actions (on advertising, marketing, labeling)
 - Insurance litigation/coverage for underlying tort litigation
 - Commercial disputes/Intellectual property issues

HOW to conduct risk management for nanotechnology products?



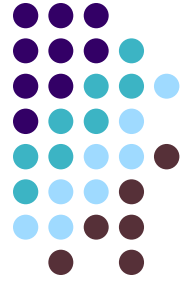
- Protecting the business requires planned product risk management across the life cycle of the product
- Adapt protocols developed for drugs and devices

HOW to conduct risk management for nanotechnology products?

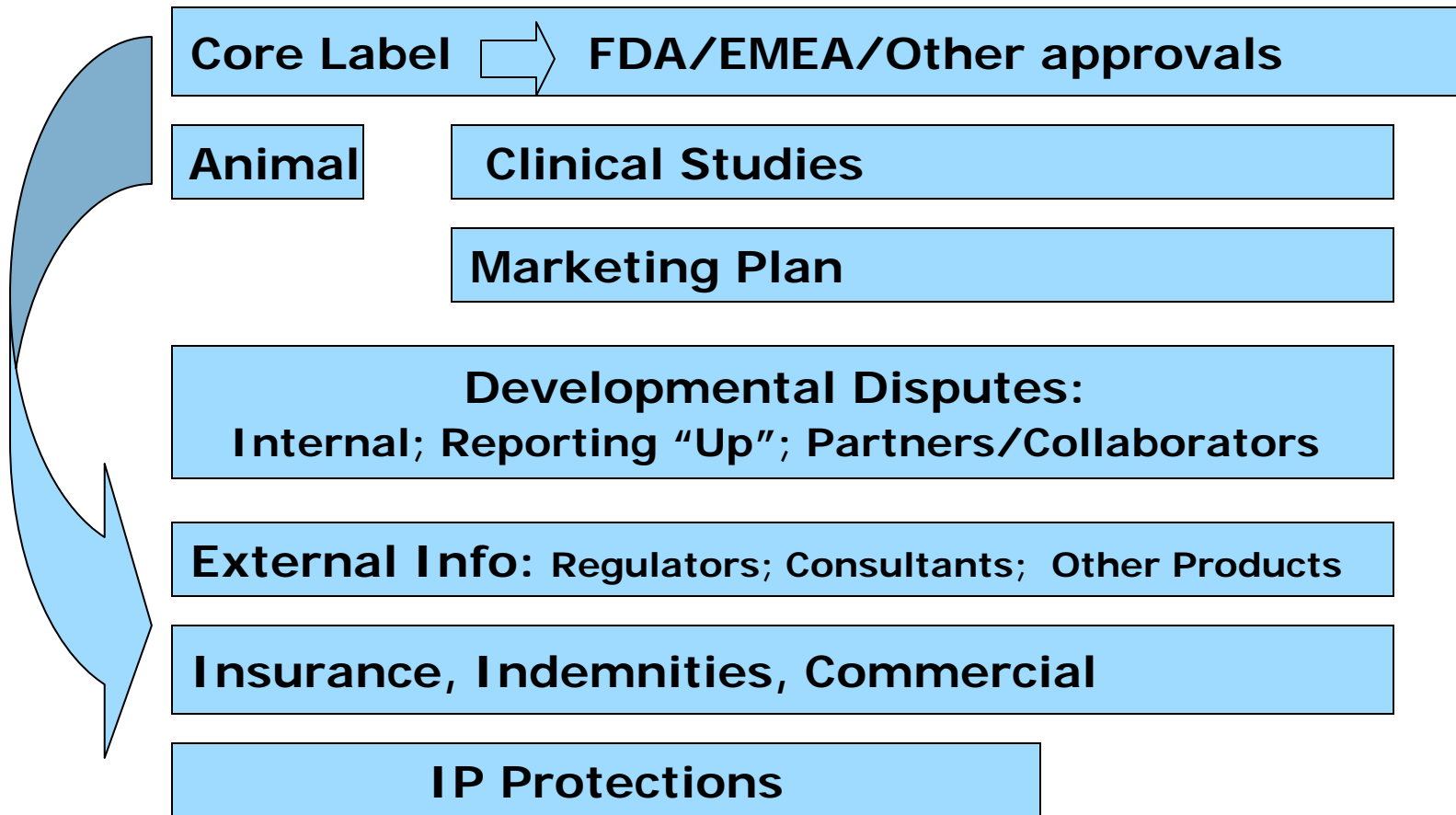


- Identify risks through an objective, independent process
- Implement risk management actions
- Prepare for post-marketing risk management

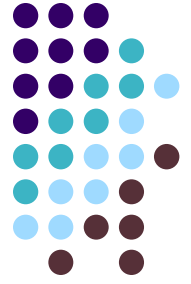
The right protocol for nanotechnology risk assessment and risk management?



- Responds to the realities of product development and marketing
 - First-in-class products
 - Siloed development
 - Co-development and co-marketing ventures
- Obtains targeted data, efficiently. Is not intrusive on the business
- Independently vets risks and risk management actions

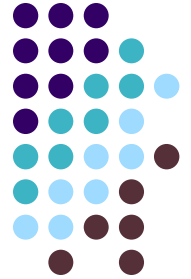


Strategic components of risk assessment



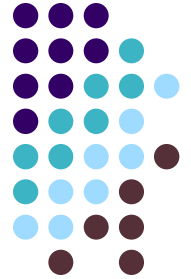
- Access to key personnel: scientific, medical, marketing, regulatory
- Access to, securing key documents
- Scope of review
- Information outside the company
- Roles of inside, outside counsel
- Privilege issues

Timing of litigation risk assessment: before marketing



- In time to take corrective actions
- At key points in development
 - End of animal studies
 - End of Phase II studies
 - Six months before launch (at the latest)
- Multiple points is more efficient

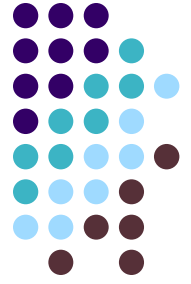
Examples of premarketing risk management actions



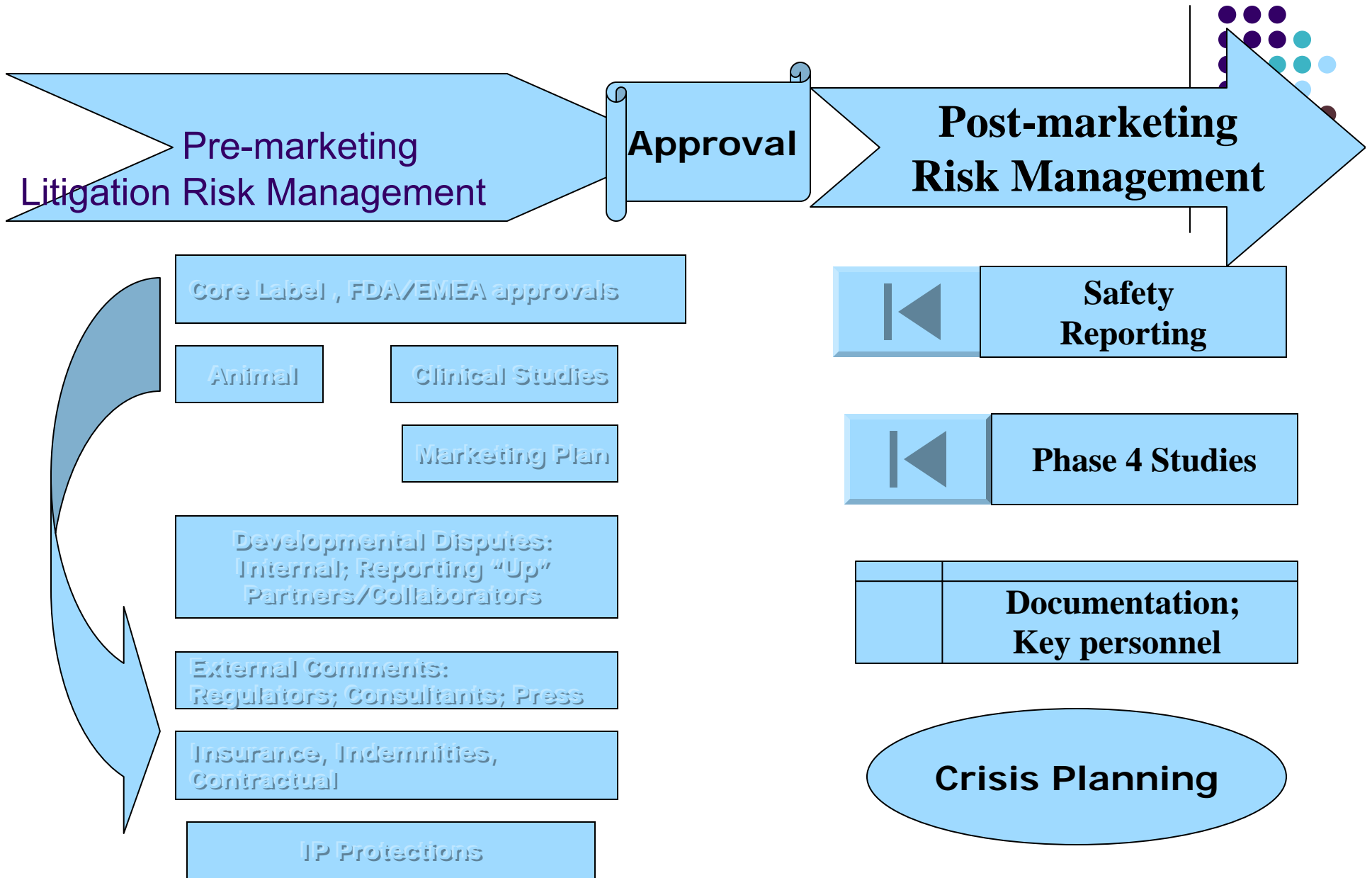
- Label change
- Marketing restriction
- Change in safety reporting plan
- Commit to specific phase 4 studies
- Enhanced record of regulatory communications and company decisions

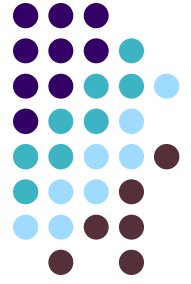


(Examples, cont.)



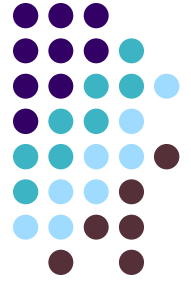
- Location and securing of documents; tracking personnel
- Resolve partner dispute
- Change in insurance or commercial arrangements
- Change in communication with regulators





Crisis planning

- Do you have a crisis management plan?
- Is the plan clear, concrete and practiced?
- Does the plan cover all internal and external communications?
- Have you done everything in advance that you can (and there is lots that you can do)?



Have questions?

Need detailed protocols for risk management or crisis planning?

- Contact Stephanie Scharf, Ph.D., J.D.
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