

Regulatory Analytics: Strategic Insights Beyond Compliance and Efficiency

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DIA

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Agenda

- ▶ Definitions
- ▶ Why Regulatory Analytics?
- ▶ Variety of Regulatory Information
- ▶ Information Explosion
- ▶ Types of Analytics
- ▶ Examples of Regulatory Analytics
- ▶ Content Analytics
- ▶ An Integrated Approach to Regulatory Analytics
- ▶ Key Messages

Definitions

▶ Analytics

- Defined as the discipline of transforming data into insights to make better decisions

▶ Regulatory Analytics

- Defined as the discipline of transforming regulatory information (data, documents and knowledge) into insights to make better regulatory and business decisions

Why Analytics?

► Benefits of analytics:

- Insights into difficult problems
- Improved processes and breakthrough efficiencies
- Improved productivity and performance
- Cost savings and increased revenues
- Accurate predictions, plans, and forecasts
- Better pricing/greater market share
- Better asset utilization
- Superior/faster ROI

Why Regulatory Analytics?

- ▶ Need for greater insights
 - Generate better insights to inform and transform early stages of regulatory strategy
 - Develop better understanding of HA regulatory processes and timelines
 - Better planning of internal resources and capabilities
 - Improve product impact assessments due to manufacturing change control or regulatory changes
 - Improve supply chain readiness for product release
- ▶ Harness the power of vast amounts of information beyond reasons of compliance and efficiency

Variety of Regulatory Information

Regulatory Strategy

- Regulatory guidelines and interpretations
- Regulatory intelligence

Submission Plans

- Regulatory submissions plans
- Table of content plans

Data and Documents

- Source Documents and Data

Submissions

- eCTD outputs
- Paper outputs

HA Correspondence

- HA Questions
- HA Correspondence

Registrations

- Registration data
- Lifecycle information

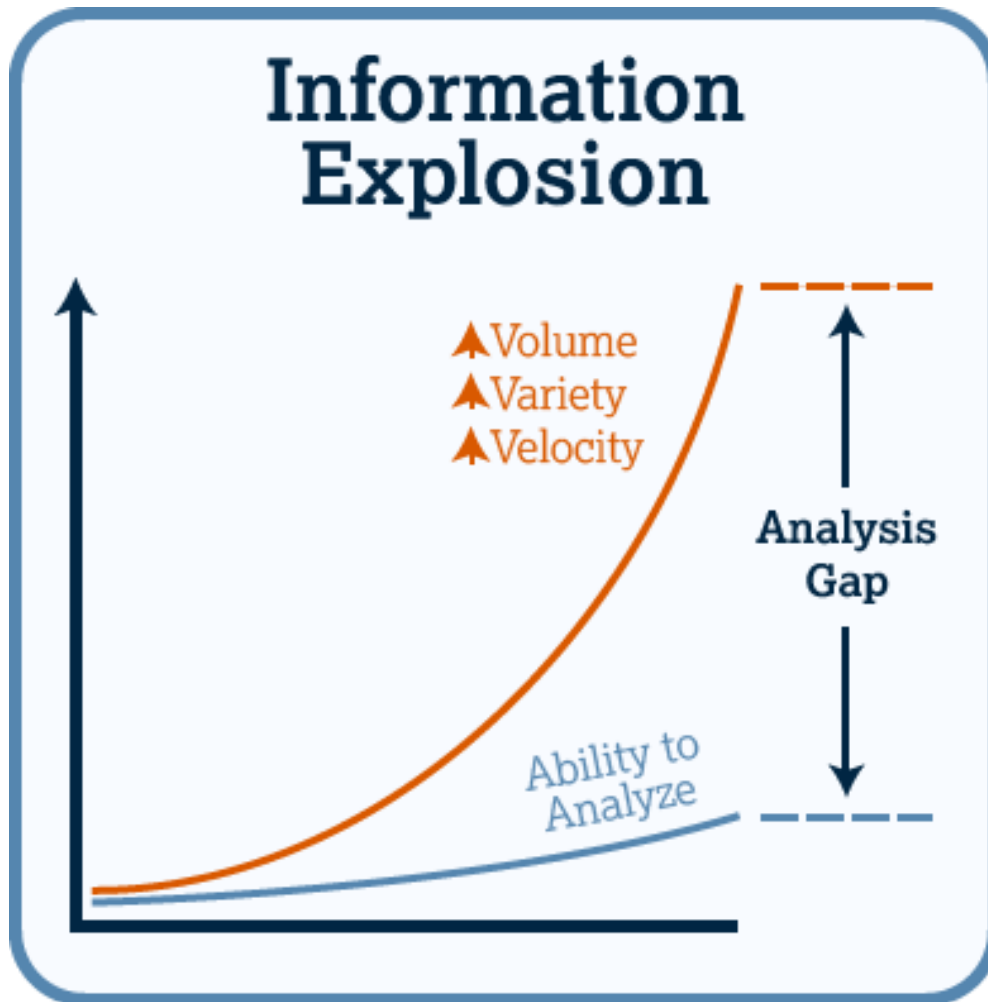
HA Commitments

- HA Commitments and obligations

Archive

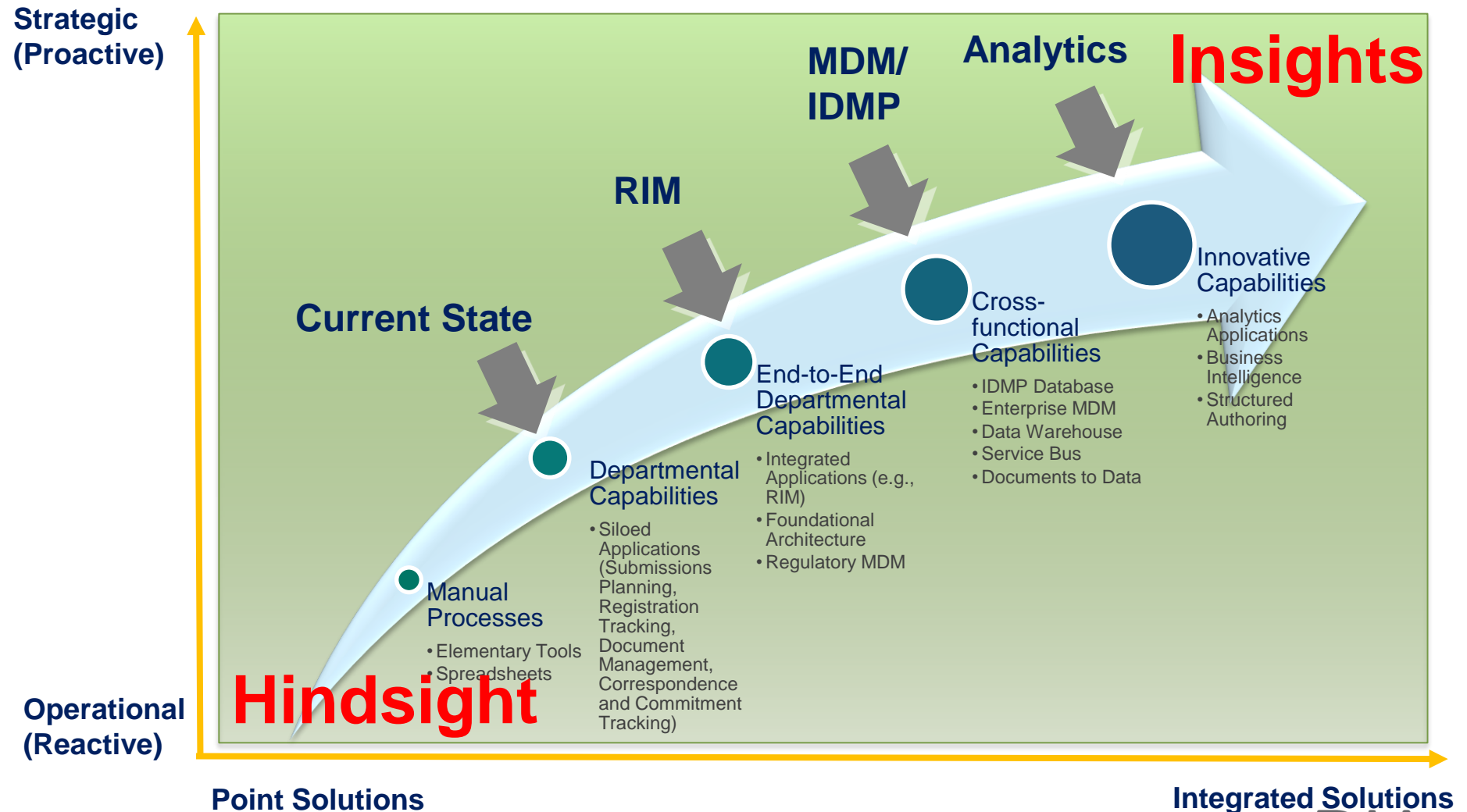
- Submissions made to HA
- Local documentation

Regulatory Information Explosion

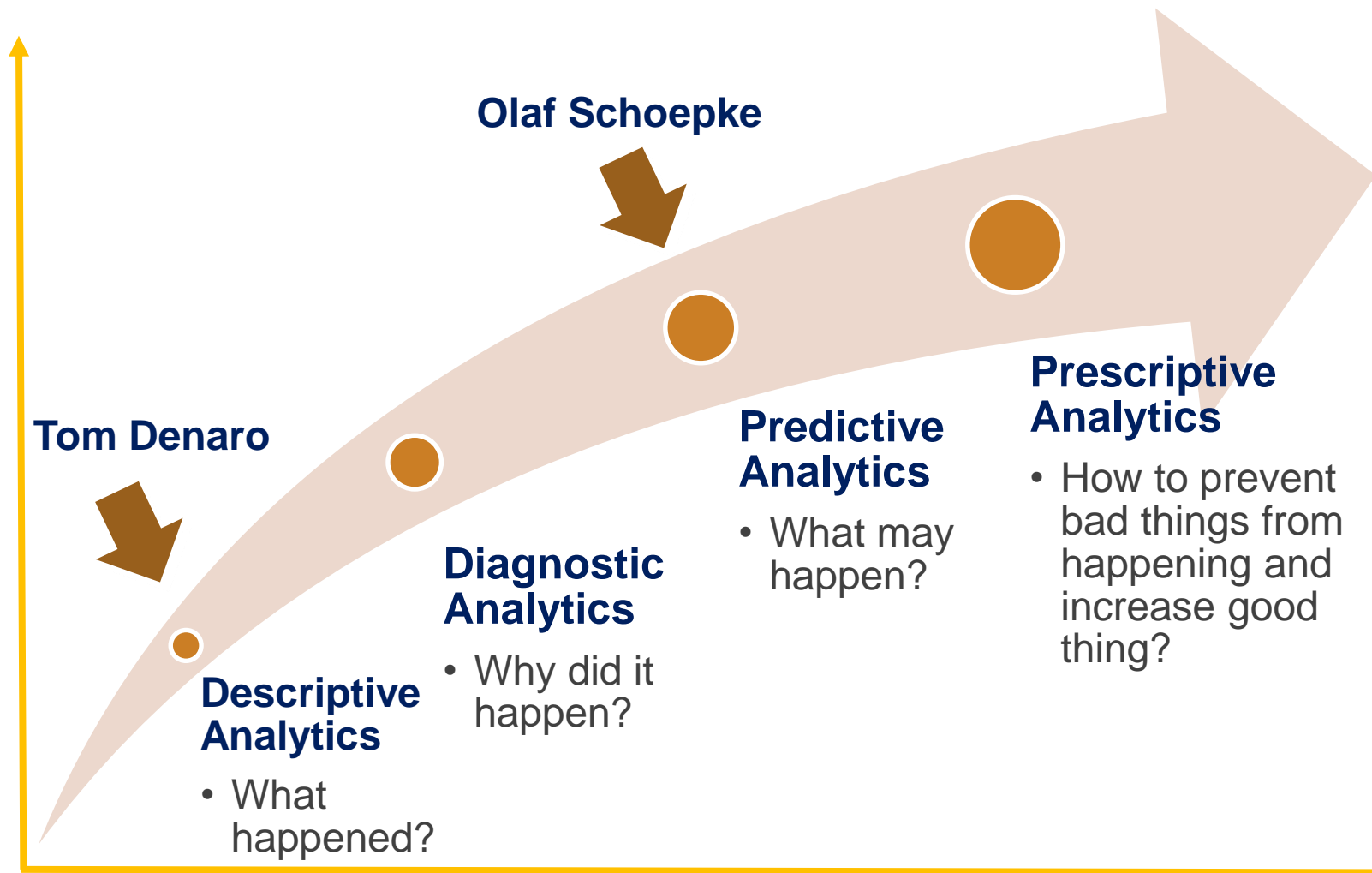


- ▶ With end to end RIM capabilities and the advent of IDMP, potential for information explosion:
 - Great variety – data, documents, knowledge
 - Huge volume - documents, data
 - Moderate velocity
- ▶ Our ability to analyze vast amounts of disparate information is limited
- ▶ How do we make sense out of this explosion?

Going from Hindsight to Insights



Types of Analytics: Maturity Curve



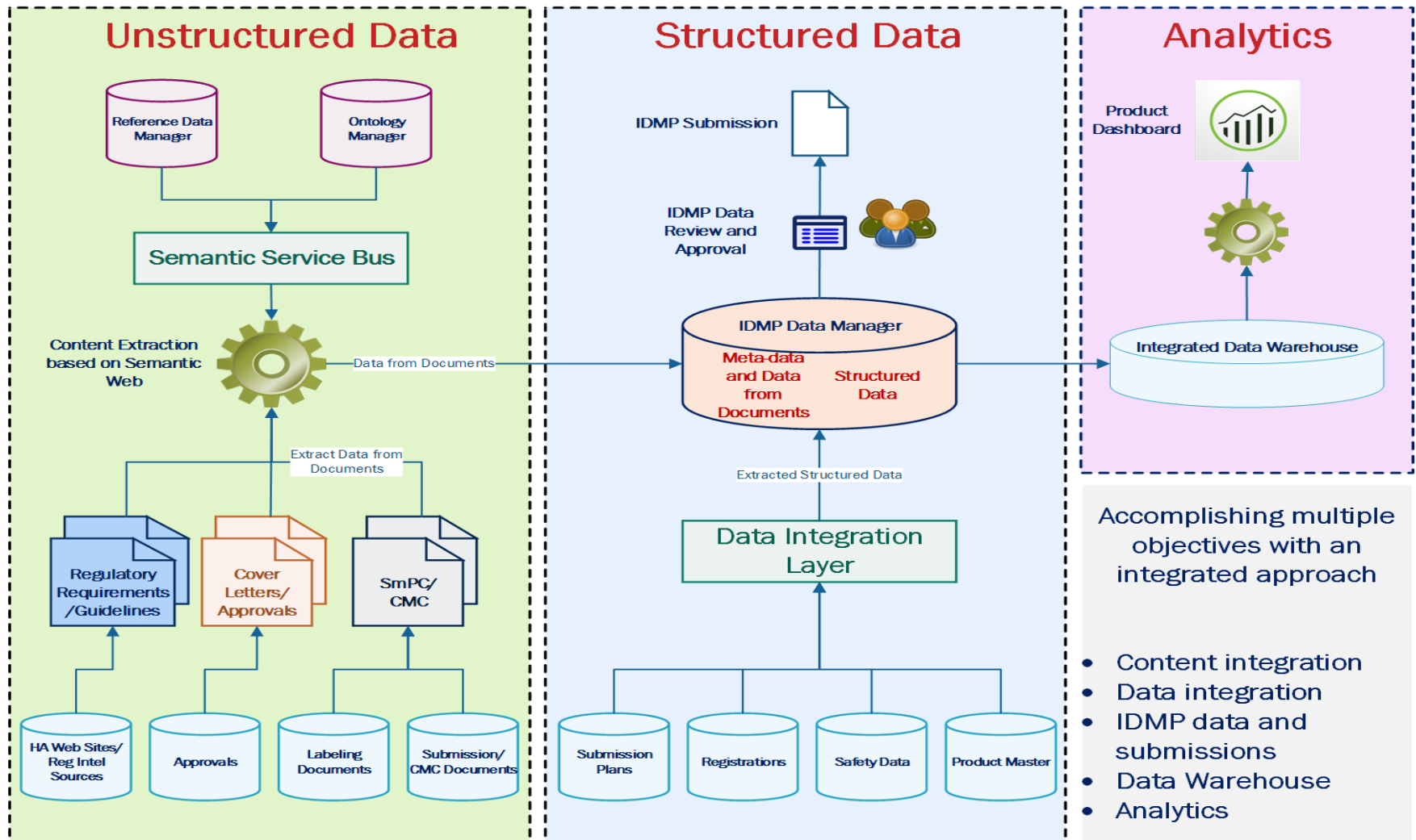
Regulatory Analytics: Examples

Type of Analytics	Regulatory Examples
Descriptive Analytics (What happened?) Traditional metrics	<ul style="list-style-type: none"> • What is the total duration taken to make a submission from the time of initial planning? • What is the total number of submissions, by country, by product, etc.? • How did we perform in our submissions over the past five submissions? • How many re-works per submission?
Diagnostic Analytics (Why did it happen?) Traditional metrics	<ul style="list-style-type: none"> • Why were there delays in making a submission to a HA? • What were the top five reasons applications were delayed over the past five submissions? • Why were there re-works on a submission?
Predictive Analytics (What may happen?)	<ul style="list-style-type: none"> • What is probability of achieving our target submissions dates? • What are the potential questions to be expected from HA? • What are the potential expected revenues based on approvals in BRIC markets? • What is the revenue impact of safety signals identified during post-marketing safety studies?
Prescriptive Analytics (Predict and Prevent)	<ul style="list-style-type: none"> • What are the best regulatory pathways for an oncology drug to get regulatory approval in Japan, for example? • Given past immunology drug approvals, what is the best strategy to apply for our current immunology submission? • What impacts may occur due to geo-political changes on approvals?

Content Analytics

- ▶ Significant amount of regulatory information is in submission documents, approval letters, correspondence, labeling
- ▶ Analysis of structured and unstructured content in emails, documents, web sites and other enterprise content repositories
- ▶ Use of semantic web technologies to extract, transform and manage content that can be mined and analyzed

An Integrated Approach to Regulatory Analytics



Key Messages

- ▶ Analytics increasingly critical for the effective and efficient functioning of the pharmaceutical business
- ▶ Regulatory Analytics becoming important as variety, volume and velocity of information increases due to integrated RIM (and IDMP)
- ▶ Go beyond descriptive analytics or metrics to higher order analytics, more prescriptive and predictive
- ▶ Content analytics becoming key to extracting insights from documents
- ▶ Data integration from structured and unstructured sources key to an effective Regulatory Analytics strategy

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