Life Sciences and Analytics SAS 2.0

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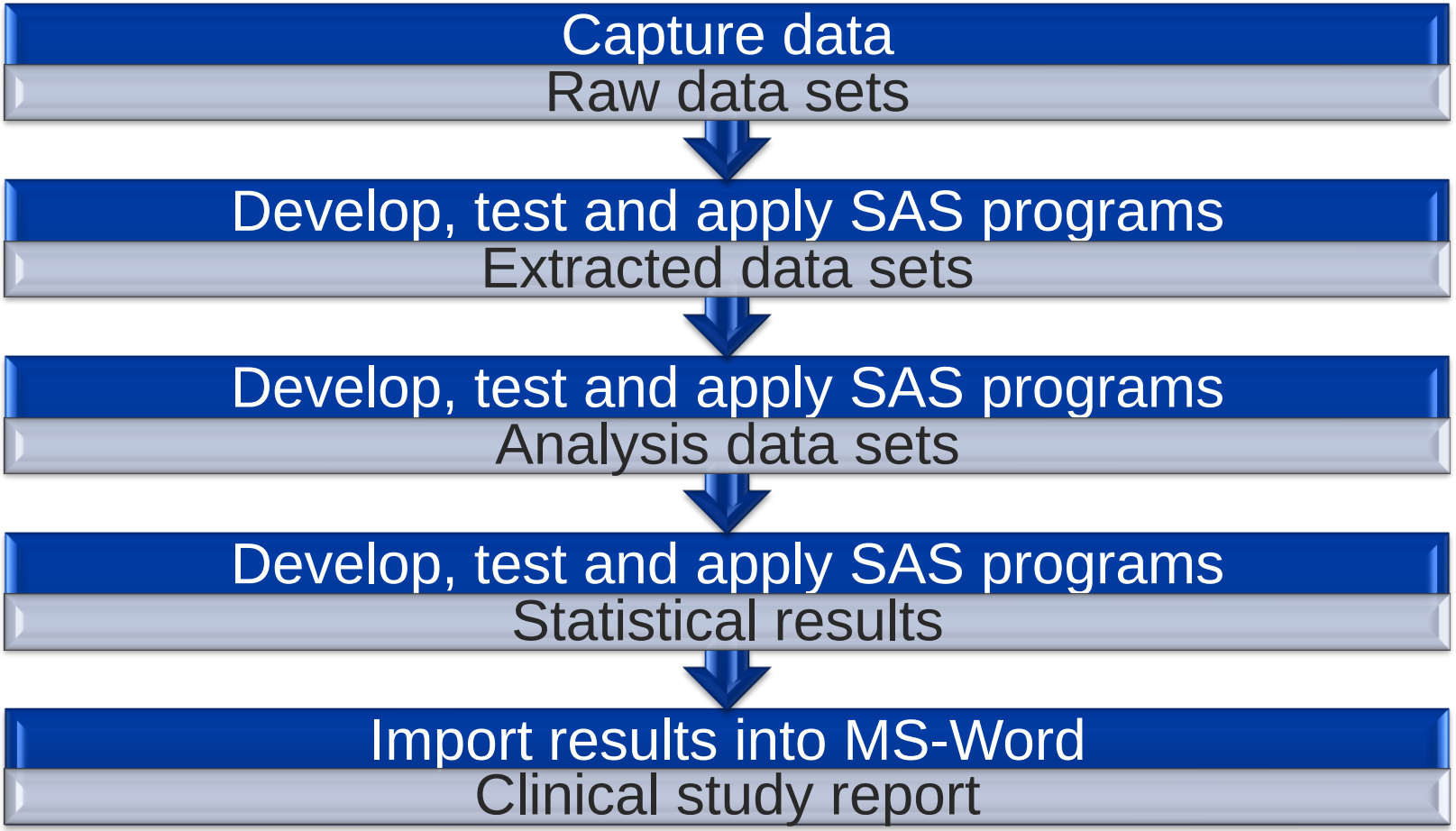
Life Sciences and Analytics
SAS 1.0



Principles Guiding SAS Health and Life Sciences

1. The health and life sciences ecosystem is broken.
2. Deeper insights into patients and organizations are needed to improve it.
3. These insights will come from a new era of industry analytics.
4. These analytics will rely on data found all across the ecosystem.

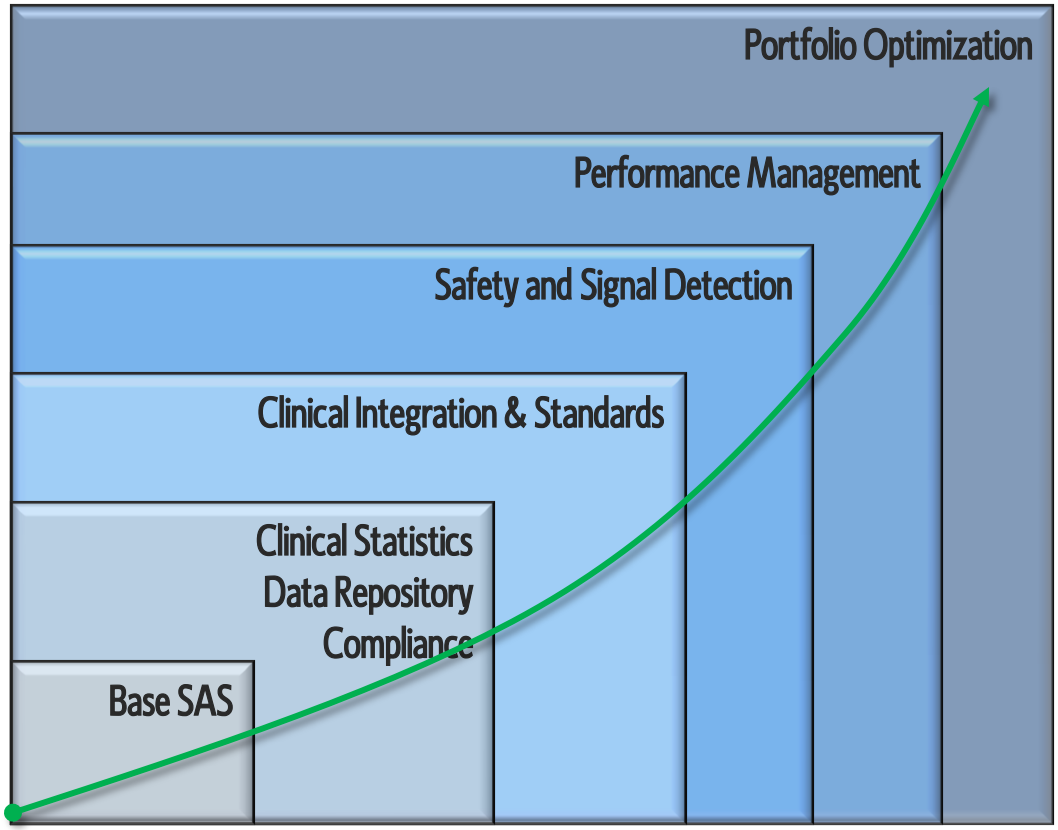
The SAS Health and Life Sciences Strategy

- Vision:
  SAS will be the compliant, integrated platform on which the health and life sciences industries derive scientific and business insight.

- Fundamental Belief:
  The future innovations in healthcare, health plans, and life sciences will be powered by information shared across these historically distinct market segments with convergence around patient data.

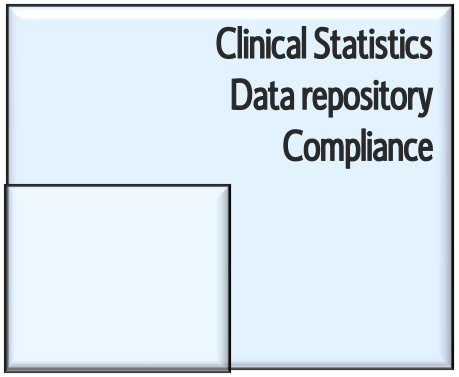
Life Sciences R&D – Moving Into The Future

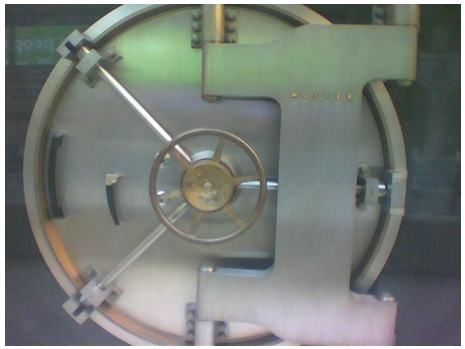
- Hierarchical set of business capabilities
- Consistent information chain for decision-making
- Power of analytics at one level can be leveraged by analytics at other levels



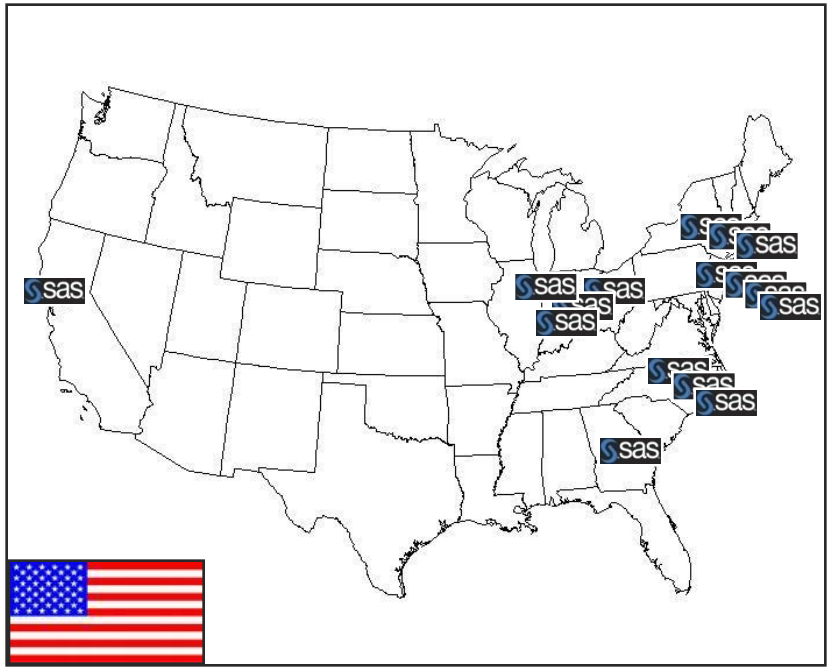
SAS Drug Development

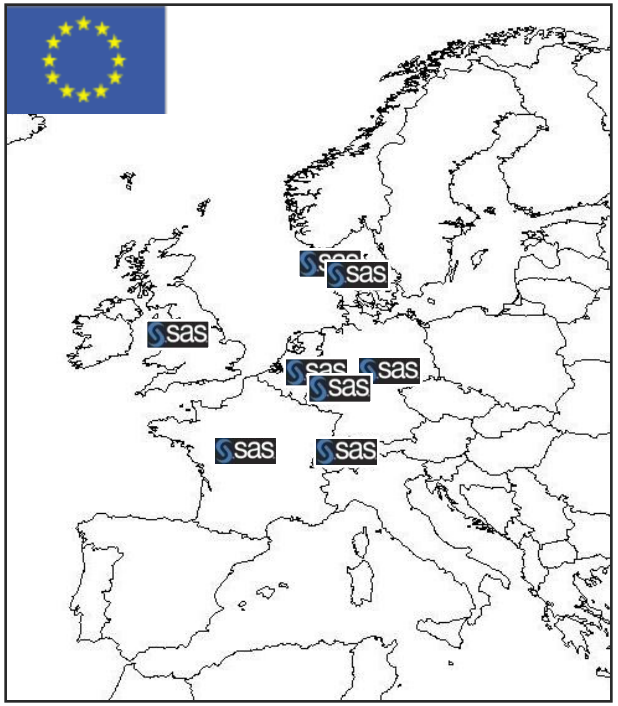
- An integrated system for developing, managing, validating, and reviewing SAS reports and analyses within and across research studies
  - Controls and compliance
  - Centralized information management and processing
  - Collaborative access to address:
    - Safety and efficacy reporting
    - Inclusion of statistical results in study reports and submissions
    - Ad hoc data exploration by scientists

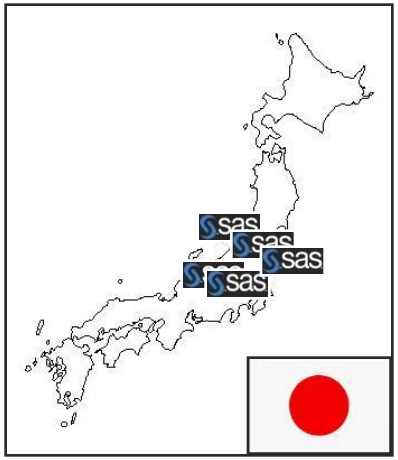




SAS Drug Development Adoption

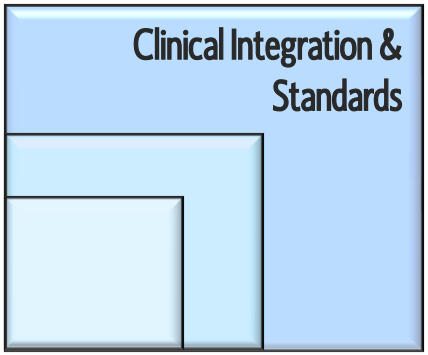






Clinical Data Integration and Standards
The business problem

Factors	Impacts	Results
• Disparate data • Inaccurate data • Incomplete data • Poorly timed data	• Multiple versions of the "truth" • Wasted effort • Poor relationships (CRO, lab, etc.) • Trial delays • Inaccurate information for management	• Bad decisions • Lost revenue • Lost productivity • Lost market opportunity



Clinical Data Integration and Standards
CDISC (Clinical Data Interchange Standards Consortium)

"The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare."

http://www.cdisc.org/about

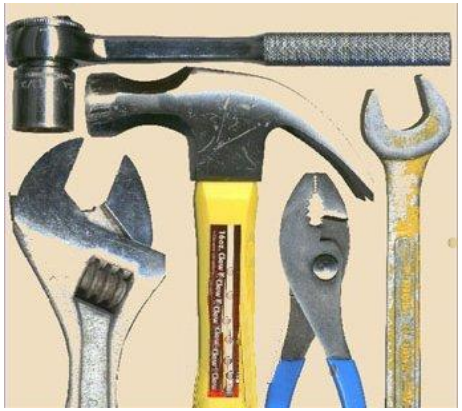
Clinical Data Integration and Standards
SAS and CDISC

- SAS is actively engaged at multiple levels with CDISC
- Ed Helton: Chairman, Board of Directors
- Dave Handelsman: Industry Advisory Board
- Ann-Sofie Bergstrom: European Coordinating Committee Charter (E3C)
- Representatives on multiple modeling committees
  - ODM
  - ADaM
  - CRT-DDS (define.xml)
  - SDTM
  - Protocol Representation
- Active involvement in FDA pilots

Clinical Data Integration and Standards SAS and CDISC

- SAS Clinical Standards Toolkit
- SAS Clinical Data Integration

Clinical Data Integration and Standards
SAS Clinical Toolkit



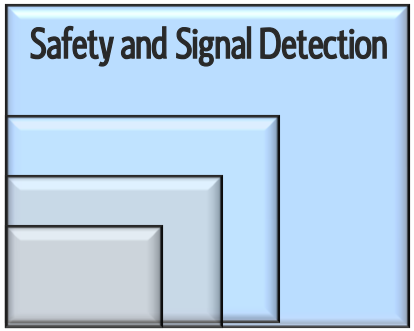
- Provides
  - SDTM validation
  - define.xml (CRT-DDS) creation
- Will ultimately include functionality beyond CDISC
- Will be available for no additional license fees beyond SAS/Base licensing

Clinical Data Integration and Standards
SAS Clinical Data Integration Solution

- Enterprise data integration strategy vs. code that satisfies one integration scenario
- A set of automated, repeatable, managable processes
- An end to end, metadata driven data integration platform
  - Data standardization
  - Data cleansing
  - Data quality
  - Master data management
- Pre-built support for CDISC
- Extensible to other standards
- Integrates disparate systems

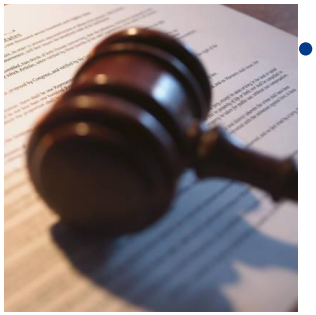
How is Drug Safety done today?

- Not timely, manual, inconsistent, non-standard
- For pre-approval analyses
  - Every company uses SAS to perform similar analyses
  - Every company uses SAS **differently** to perform similar analyses
- For post-approval analyses, ad hoc tools and processes are used



What's different in 2008?
New regulations and guidelines

- New Safety Guidances Pre and Post Approval
  - Adverse Event Reporting – Improving Subject Protection
  - Drug Safety Information – FDA's Communication to the Public
- FDA Good Review Practice / Clinical Review Template
  - Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review



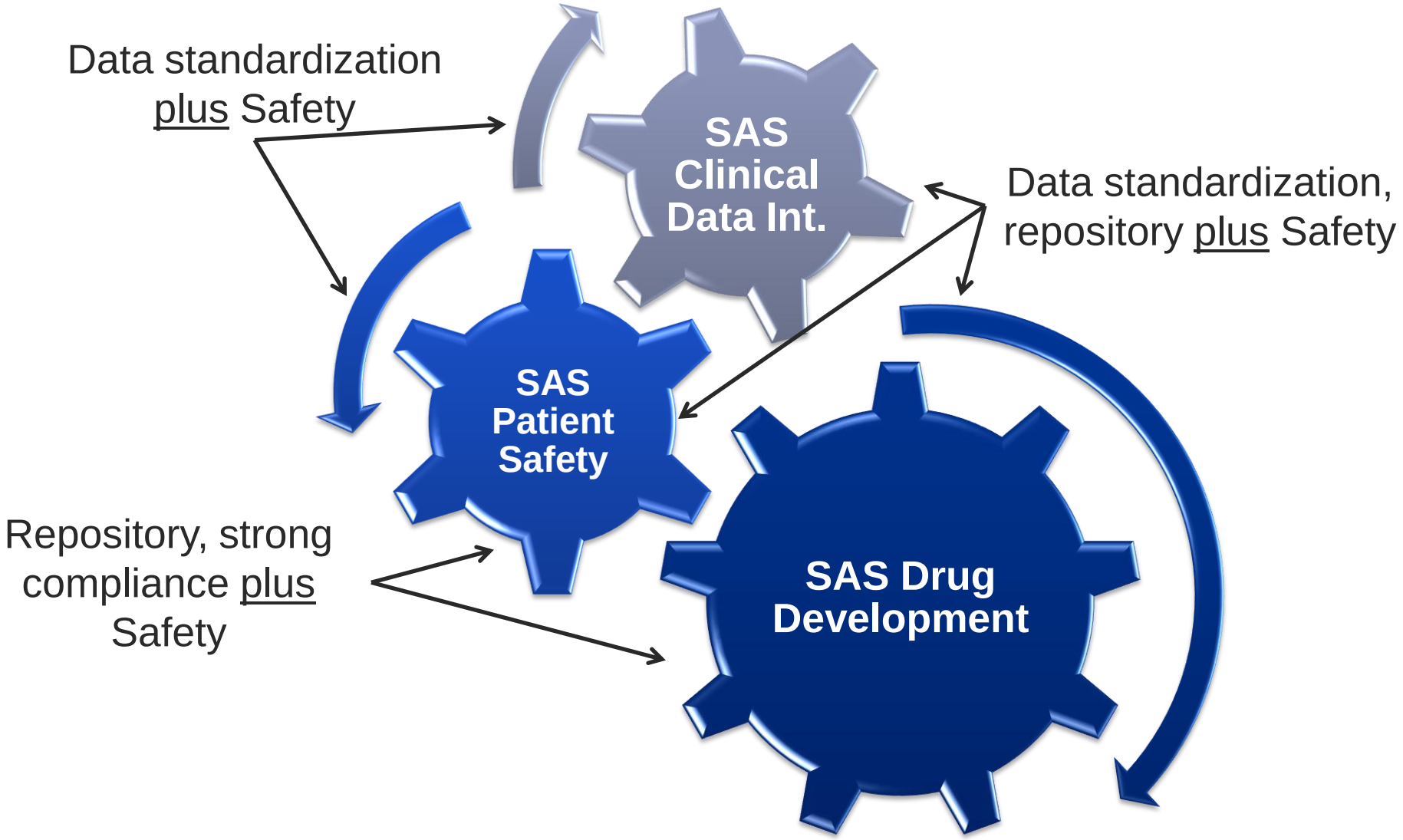
What's different in 2008 ?

- Customer tools are dated
  - Do not address new FDA guidances and practices
  - Ad hoc only for advanced analytics
- Industry data standards (CDISC) are being implemented
  - Standard data leads to standard reports

What's different in 2008?

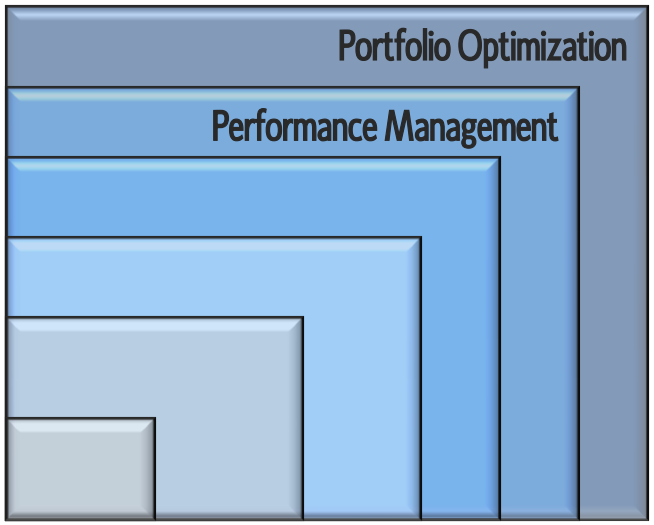
- SAS has packaged capabilities that
  - Address new safety guidances
  - Provide pharmacovigilance / signal detection
  - Enable comprehensive safety management
- These capabilities are part of a SAS platform offering that can address these and more issues

SAS Integrated Capabilities for Life Sciences



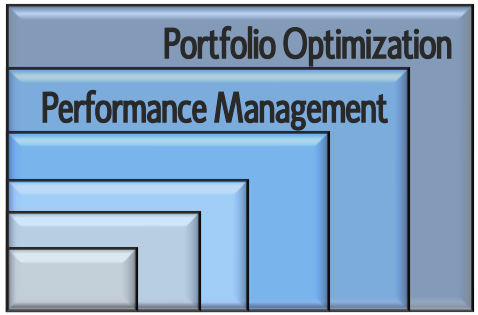
SAS Performance and Portfolio Management

- Represent longer-term investments
  - Existing horizontal capabilities today
- Will leverage multiple sources of information within analytics
  - Clinical
  - Financial
  - Market research
  - Sales
  - Safety
- “Bottom up” and “Top down” views of the business



SAS Performance and Portfolio Management

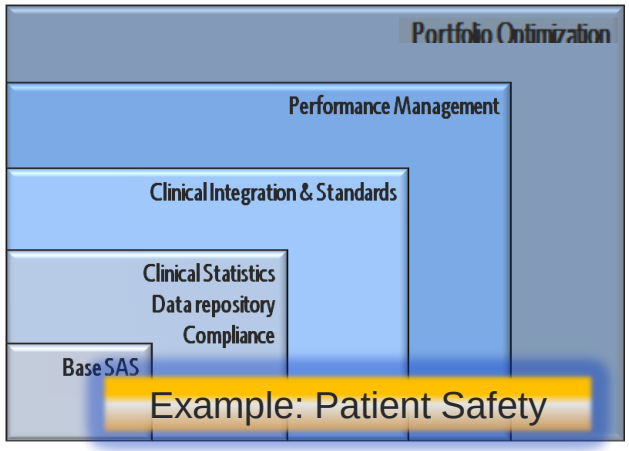
- Operational questions to answer
  - How is “study x’ performing?
    - Recruitment
    - Financially
    - Etc.
  - How should ‘study x’ be performed?
- Strategic questions to answer
  - Balancing predicted revenue vs. risk
  - Where should we invest?
  - Where should we stop investing?

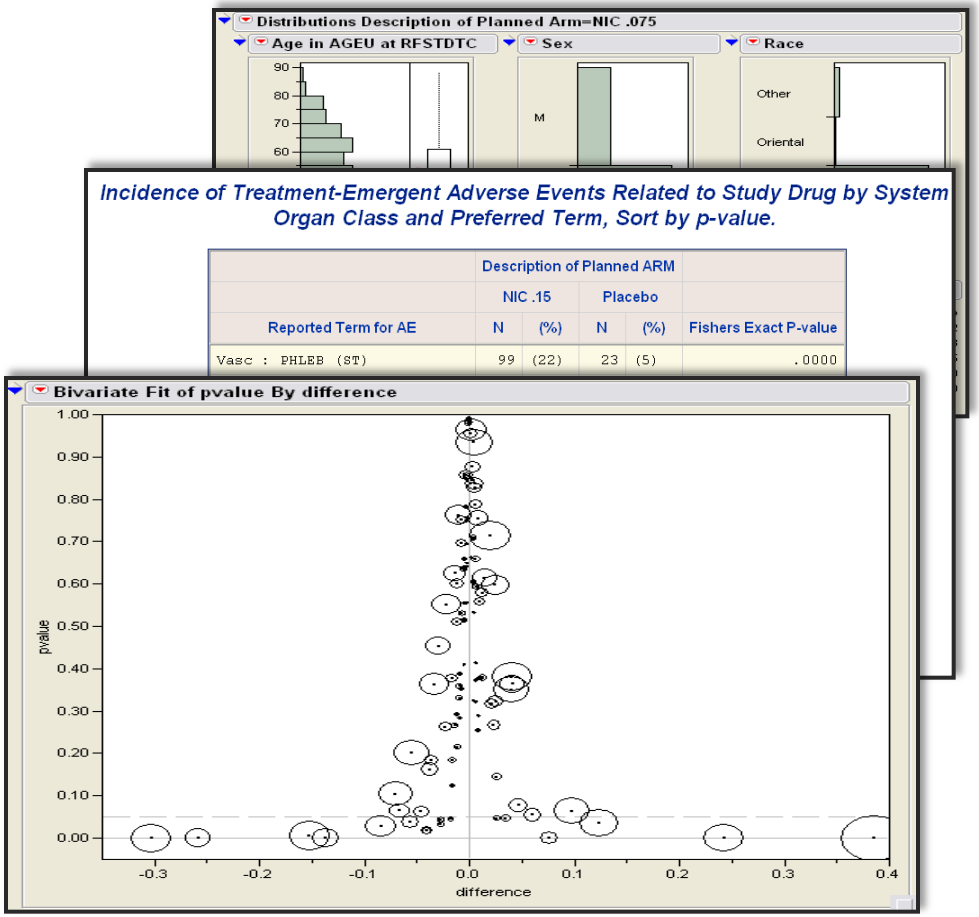


SAS Beyond Life Sciences R&D

- Manufacturing
  - SAS Demand Forecasting for Pharmaceutical Manufacturing
- Sales and Marketing
  - Maximizing the efficiency of sales and marketing spending
  - Analytics can optimize:
    - Size, allocation and deployment of sales representatives
    - Key factors that drive prescriber behavior
    - Promotional mix (sales calls, e-detailing, samples, etc)

The Power of a Comprehensive Platform





- Ask better questions; get better answers
- Standardize and automate
- Align to regulators

SAS Highlights at PharmaSUG 2008

Name	Title	Day / Time	
Pete Villiers	SAS, CDISC and Clinical Data Integration	M	8:30
Dan Heath	Effective Graphics Made Simple Using SAS/GRAPH® ”SG” Procedures	M	9:30
David Duling	From Soup to Nuts: Practices in Data Management for Analytical Performance	M	11:00
Maura Stokes	New SAS Statistical Software: Just Over the Horizon	M	1:30
Tony Friebel	Power up XML with SAS	M	2:30
Dawn Hopper	SAS® Certification: Are You Ready to Put Your SAS Skills to the Test?	M	4:00
Cynthia Zender	Creating Complex Reports	T	8:00
Teresia Arthur	Web-Enable Your SAS® Applications	T	9:30
Vince DelGobbo	Tips and Tricks for Creating Multi-Sheet Microsoft Excel Workbooks the Easy Way with SAS®	T	1:30
Maura Stokes	An Introduction to SAS® Stat Studio for SAS/STAT® Users	T	3:30
David Olaleye	Automated Drug Safety Signal Detection with Guided Analysis	W	8:30
Industry+SAS	Panel Discussion: Regulatory Submissions and CDISC Standards	W	10:00
Elizabeth Ceranowski	SAS Abbreviations are your friends, use a template method to code!	W	11:00

SAS Highlights at PharmaSUG 2008

- SuperDemos – In the exhibit hall at scheduled times throughout the conference
  - SAS Certification Preparation at Your Fingertips
  - SAS and JMP® Integration Featuring JMP Genomics
  - You Want *ME* to use Enterprise Guide??
  - Techniques for Writing SAS Programs in SAS Drug Development
  - SAS/Graph; Graph Template Language
  - SAS Stat Studio
  - SAS, CDISC and Data Integration Studio
  - Interactive Patient Safety Exploration

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SAS will be the compliant, integrated platform on which the health and life sciences industries derive scientific and business insight.