DATA MANAGEMENT • BIOSTATISTICS • PROGRAMMING • MEDICAL WRITING • PHARMACOVIGILANCE

Quanticate

A PASSION FOR EXCELLENCE

A balanced approach to efficiency

Daniel Carden, daniel.carden@quanticate.com

Global Solutions from the World's Largest Data-Dedicated CRO

www.quanticate.com

Structure

- Background
- Introduction
- Program efficiency: theory and application
- Data efficiency: theory and application
- Summary

Background

- Efficiency: the extent to which a resource is used for the intended purpose (to produce approved drugs)
- Innovation is aimed at increasing this efficiency
- Accounting cost and opportunity cost

- Accounting cost

Research and Development spending, £42 billion in 2011 [a]

- Opportunity cost

Losing patent time. Top 80 drugs had sales > £800m per year [b]
Label restrictions = sales to a smaller market

Introduction

Balanced approach

- Overall efficiency vs. micro efficiencies
- Overall efficiency is the goal
- Aim is to understand the importance of each micro efficiency

Two discussion points

Program efficiency (costs in time and money)
Number of micro efficiencies

Data efficiency (costs of data, accounting and opportunity)
One micro efficiency: initial accounting cost

Program efficiency: theory

Quanticate
A PASSION FOR EXCELLENCE

- Effecting Efficiency Effortlessly, PhUSE 2011 [c]

Techniques to minimise program run-time, e.g. SAS views
Run-time efficiency as a micro efficiency

- Run-time techniques likely to cost the individual to implement

Time saved for individual depends on:

- How long it takes to learn the run-time techniques
- Size of data processed each run
- How many times the program is run
- Amount of run-time per run saved by the techniques

Time saved must be greater than the time cost to be worthwhile for the individual

Program efficiency: theory

Quanticate
A PASSION FOR EXCELLENCE

- Example:

20 minutes to implement a run-time efficiency technique
10 minutes to run a piece of code
Code reduces run-time by 10% of run-time (1 minute)
Code to be run 10 times

In this case not worth it as 20 minute cost > 10 minute benefit

- However, amount of run time saved per run will tend to increase with the time spent learning the techniques
- Also important is the possible cost beyond the individual

Program efficiency: theory

Quanticate
A PASSION FOR EXCELLENCE

- Contribution of run-time efficiency to program efficiency depends on context
- Dean Grundy, PhUSE 2010, ‘What makes a ‘good’ program’ [d]
- 8 software quality factors:
  - Correctness
  - Efficiency – “how much system resources the program uses”
  - Understandability
  - Maintainability
  - Timeliness
  - Robustness
  - Reusability
  - Portability – how system or platform dependent
- Short answer: “very much depends on the situation and purpose of the program”

Program efficiency: theory

Quanticate
A PASSION FOR EXCELLENCE

- Run-time efficiency as a micro efficiency. Other micro efficiencies:
  - Creation efficiency: how long it takes to write a program
  - Re-use efficiency: how long it takes to make changes to a program to produce a different output
  - Reading efficiency: how long it takes to understand what code is doing, and to validate that what it is doing is correct
  - Re-work efficiency: how long it takes to fix errors or bugs in the program, or to make updates
- Importance determined less by context: reading and rework
- Constraint of creation efficiency

Program efficiency: application

Quanticate
A PASSION FOR EXCELLENCE

- With small datasets, run-time efficiency is of secondary importance to program efficiency
- Primary importance:
  - Re-use efficiency: how long it takes to make changes to a program to produce a different output
  - Reading efficiency: how long it takes to understand what a code is doing, and to validate that what it is doing is correct
  - Re-work efficiency: how long it takes to fix errors or bugs in the program, or to make updates
- Sizeable constraint of creation efficiency
- Transparency of the programming process is hugely important

Data efficiency: theory

- Program efficiency about minimising the cost of programs
- Data efficiency about minimising the cost of clinical data. This includes collection, processing, storage, retrieval.

- Programs

Start: when data have already been entered into databases
Stop: once tables, listings and figures presenting the data have been produced

- Clinical data:

Start: at the beginning of the clinical trial, before any data have been collected
End: no fixed end point, could be as late as post-approval

Data efficiency: theory

- Balanced approach must be applied as for program efficiency
- Three areas of development pharmaceutical firms are focussing on to minimise cost:
  - Outsourcing
  - Data collection for data analysis
  - Common data standards and real-time analysis of drug performance

- Aim is to minimise overall cost of data
- Micro efficiency of initial cost of each area of development
- Balanced approach is needed to judge importance of the micro efficiency of initial cost

Data efficiency: application

- Pharmaceutical firms increasingly outsourcing
- Portion of global Research and Development (R&D) outsourced grew by 6.6% from £20 billion to £23 billion from 2009 to 2011 [e]
- According to figures by Frost & Sullivan, outsourcing reduces financial cost by 30% to 35% [f]
- Allows greater focus on the core pharmaceutical firm competencies of R&D and marketing
- Careful planning needed for it to be a success:
  - Must be clear about where cost reductions can realistically be made
  - Risk management to ensure costly errors are avoided

Data efficiency: application

- Data collection for data analysis
- Plan what data is needed in advance:
  - Increase accounting cost in the short term to plan what data is needed
  - Accounting cost may be reduced in the long term as the collection of redundant data is avoided
  - Opportunity cost may be significantly reduced in the long term as well planned data will cut the time taken to address regulatory concerns

- Difficult to know what will want to be analysed in advance, but projections based on experience can be made

Data efficiency: application

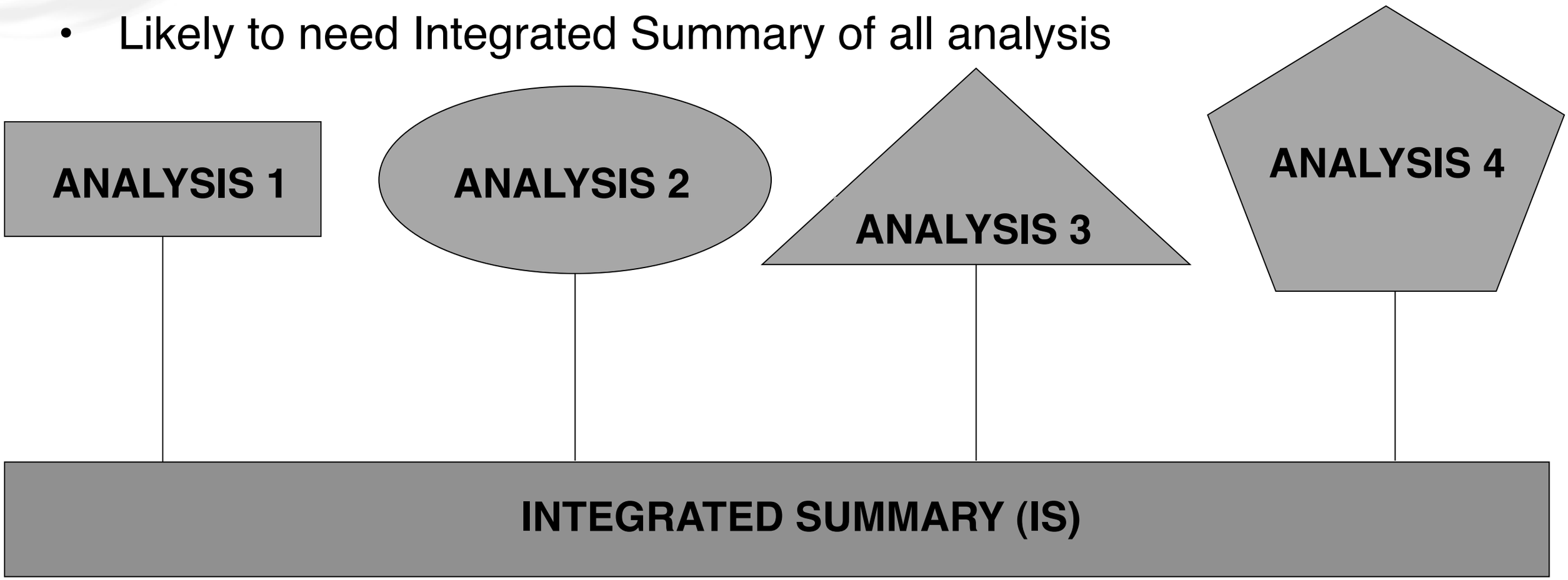
Quanticate
A PASSION FOR EXCELLENCE

Trial 1	Trial 2	Trial 3	Trial 4
Safety in subjects	Safety and efficacy	Analysis of subset of the population e.g. patients with asthma	Long term safety analysis
ANALYSIS	**ANALYSIS**	**ANALYSIS**	**ANALYSIS**

Data efficiency: application

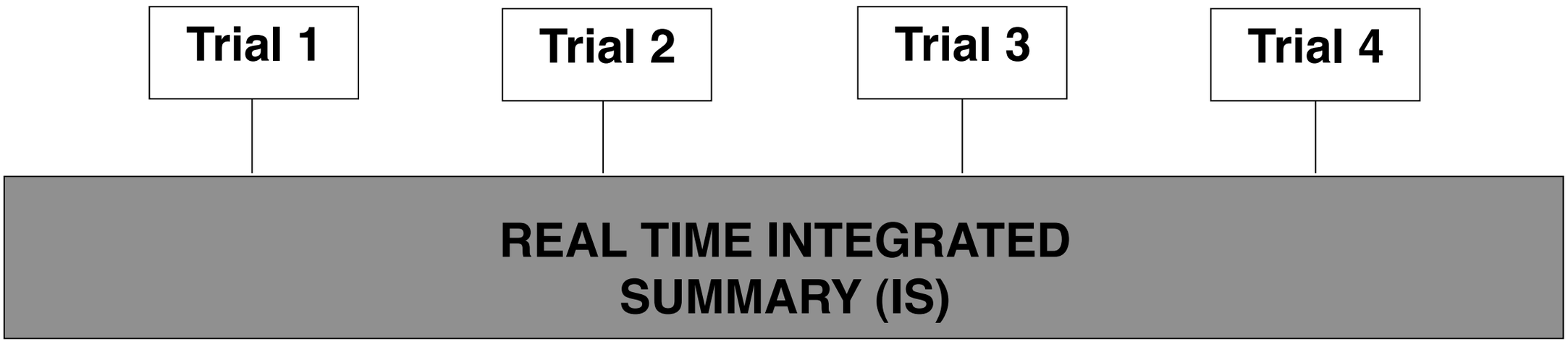
Quanticate
A PASSION FOR EXCELLENCE

- Common data standards and real-time analysis of drug performance:
- Likely to need Integrated Summary of all analysis



Data efficiency: application

- Adopting the regulatory data standard will reduce opportunity cost by allowing regulators to more easily see into the data, making analysis easier
- If the same data standard is applied across trials and a central platform to review and collate data is introduced, then there is potential to streamline the data process to:



Data efficiency: application

Quanticate
A PASSION FOR EXCELLENCE

- All three areas of development have huge potential to improve data efficiency
- The crucial consideration is that the micro efficiency of initial cost of each area of development is not confused with overall data efficiency
- Outsourcing may appear to provide inexpensive data solutions, but the process must be well managed
- Planning so that data collection is based on analysis needs will cost initially, but can make substantial cost savings and improvements to the quality of analysis down the line
- Common data standards may be initially expensive per-trial or per-drug, but the benefits will be reaped the more data collected and analysis needed

Summary

- Pharmaceutical industry needs to make efficiency gains
- R&D spending per drug currently ranges from £2.4 billion to £7.6 billion per drug depending on firm [i]

- Balanced approach is necessary to distinguish between micro efficiencies and overall efficiency
- Program efficiency: many micro efficiencies were discussed all of which contribute to program efficiency to varying extents
- Data efficiency: the significance of the micro efficiency of initial cost was explored for three growth areas of data cost management; outsourcing, data collection for data analysis and common data standards

References

- [a] CMR International (June 2011)
- [b] MedAdNews 200 - World's Best-Selling Medicines, MedAdNews (July 2007)
- [c] Effecting Efficiency Effortlessly, Daniel Carden, Quanticate Ltd (PhUSE 2011)
- [d] What makes a ‘good’ program?, Dean Grundy, Roche Products Ltd (PhUSE 2010)
- [e] Report: Over one third of clinical trials are outsourced by pharma companies (web source: centerwatch.com)
- [f] Outsourcing in Pharmaceutical Industry, Swati Chaturvedi, (web source: bionity.com)
- [g] Improving focus, Jo Pisani and Graham Pascoe, PricewaterhouseCoopers LLP (web source: pharmaceuticaloutsourcing.com)
- [h] Producing comprehensive integrated summaries, Michael Whitworth, Quanticate Ltd (Journal of Pharmaceutical Programming, 2011) *NOT CITED*
- [i] The Truly Staggering Cost of Inventing New Drugs, Matthew Herper, Forbes (February 2012)