

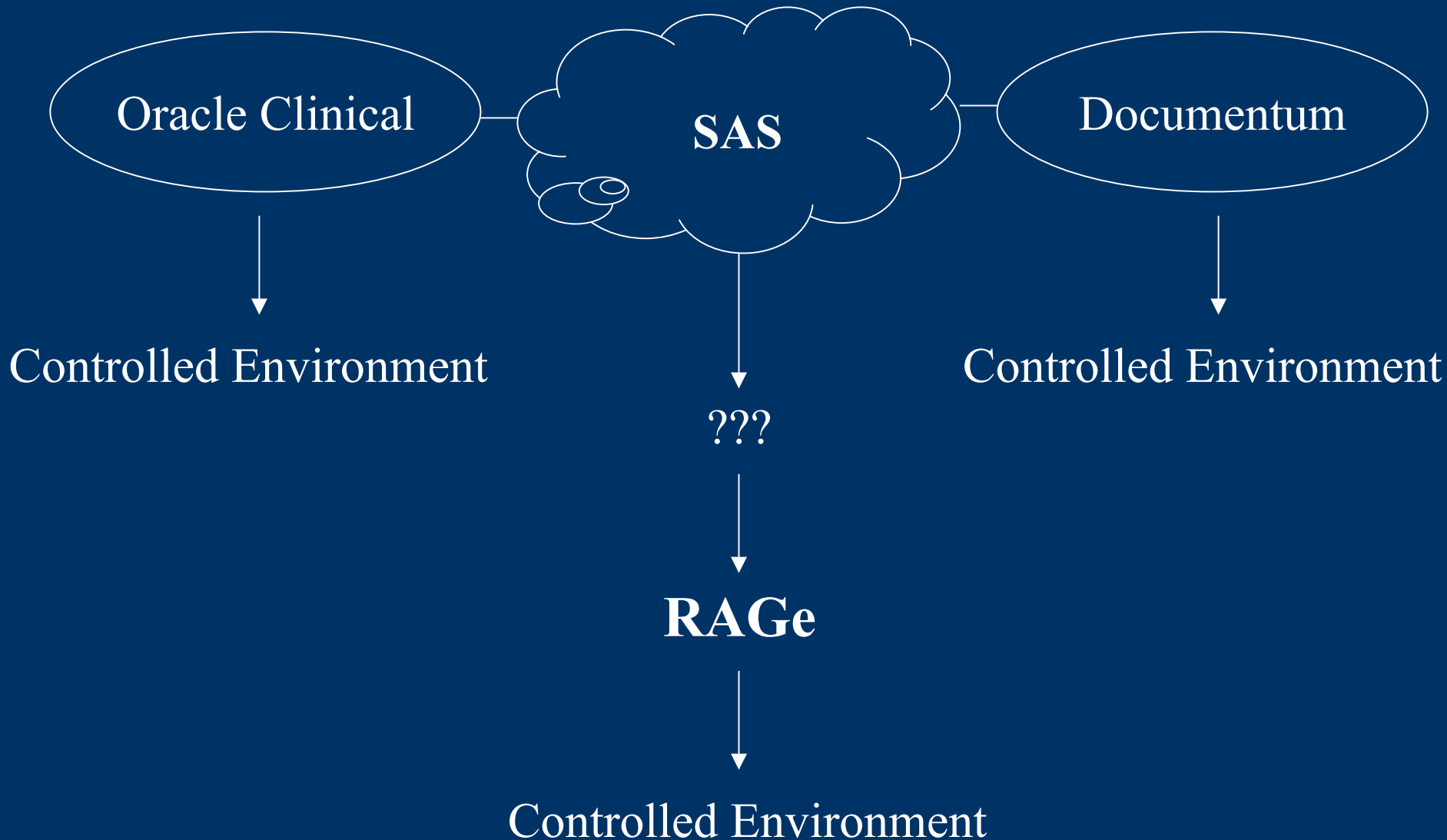
From Data Entry to e-submission – only a button away with SAS. Integrated Clinical trial reporting
- Oracle Clinical, SAS and Documentum

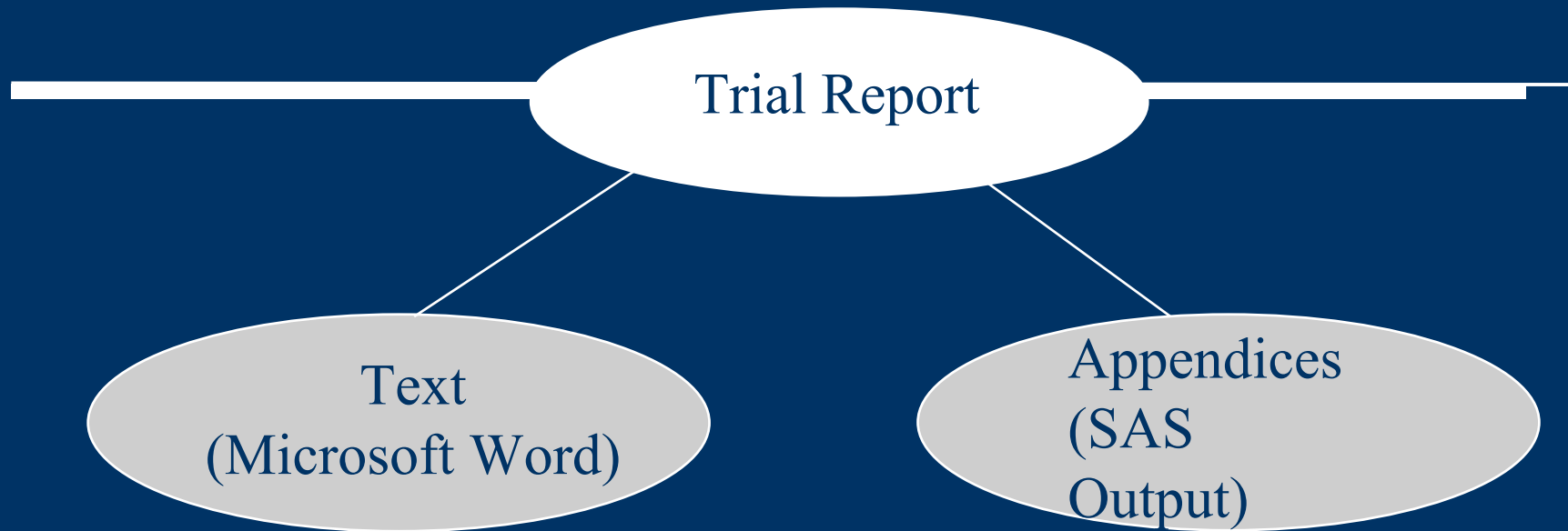
Andy Lawton and Michael Pearce

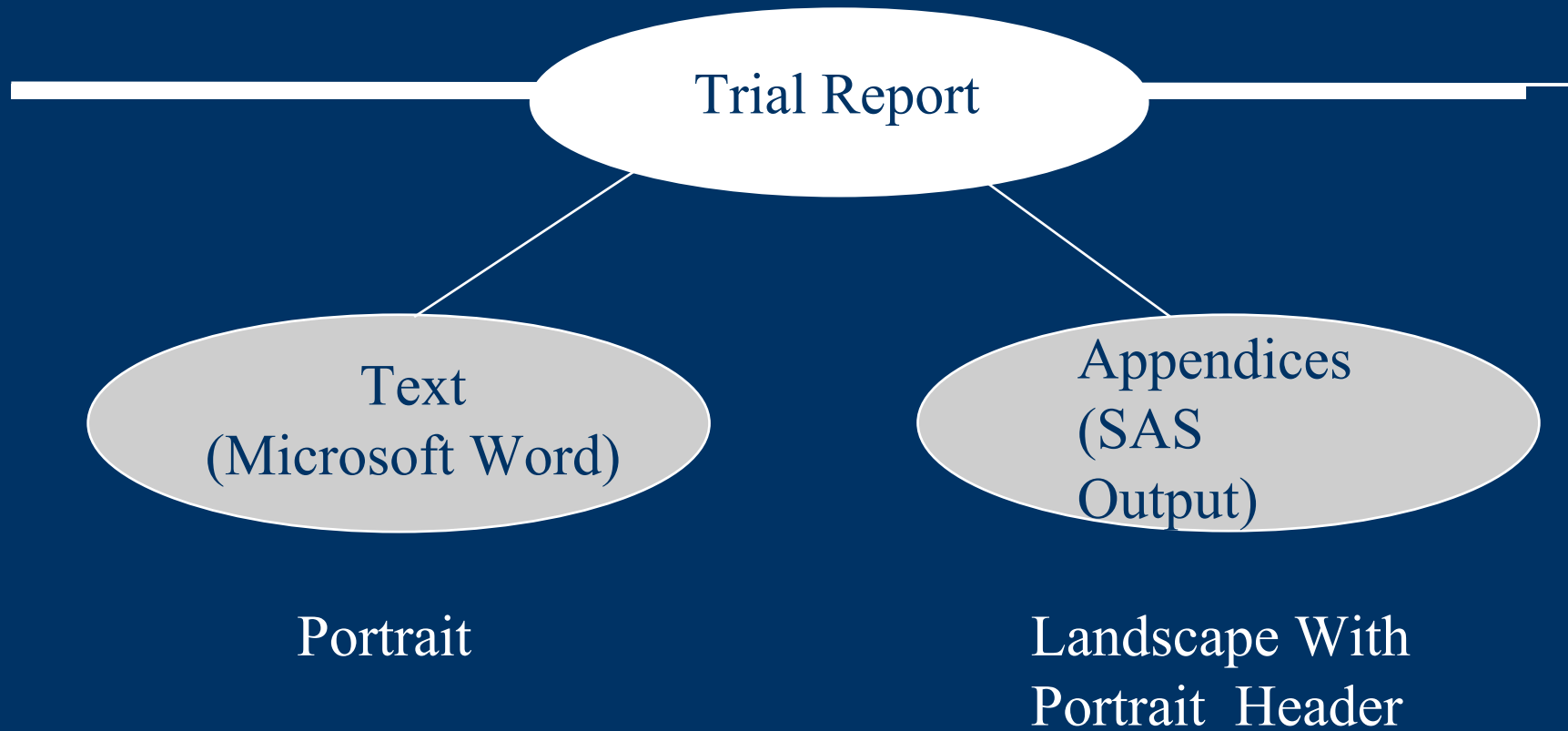
Boehringer Ingelheim Limited (UK)

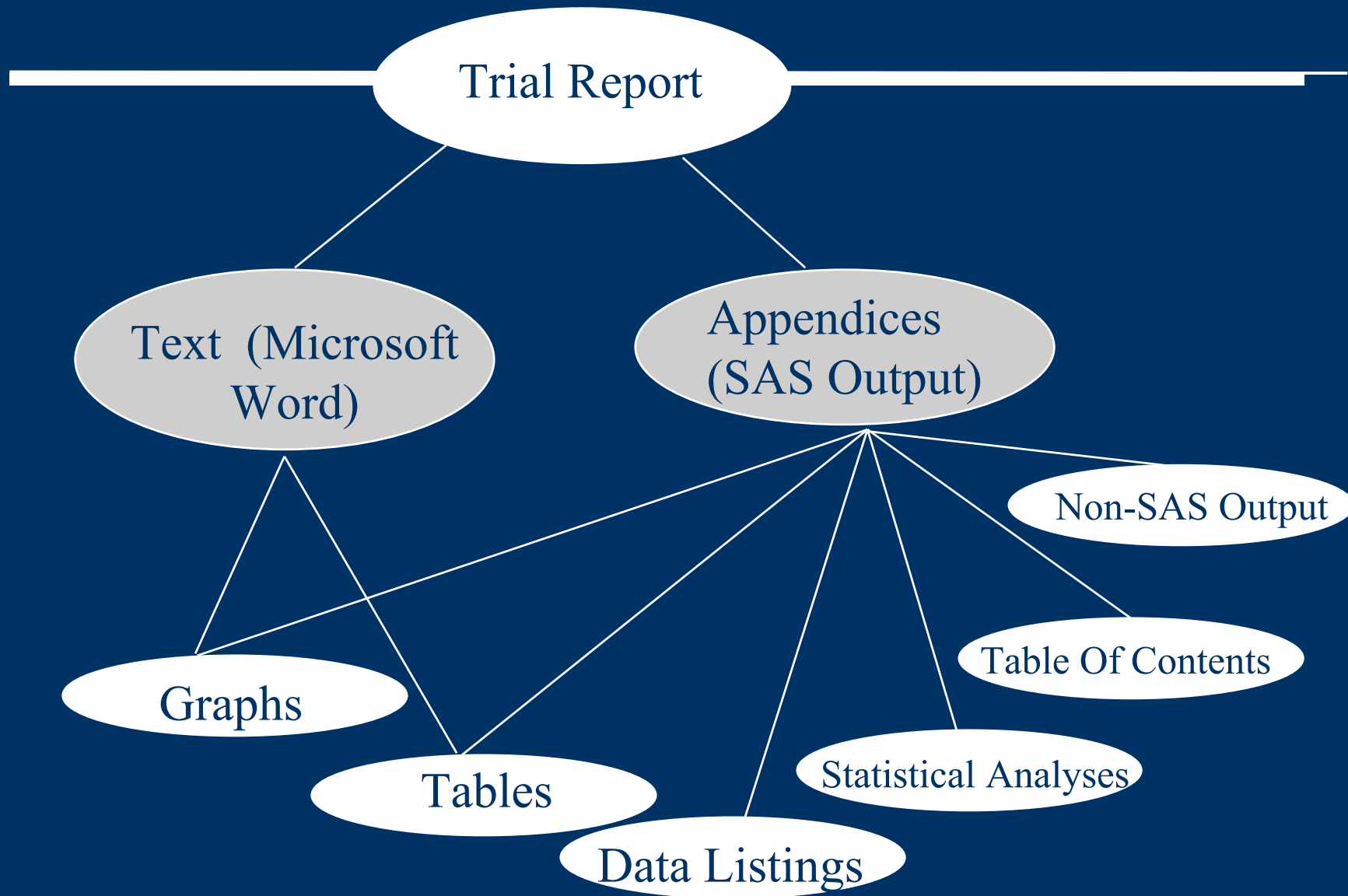
The Generalised Problem - Producing Trial / Project Reports

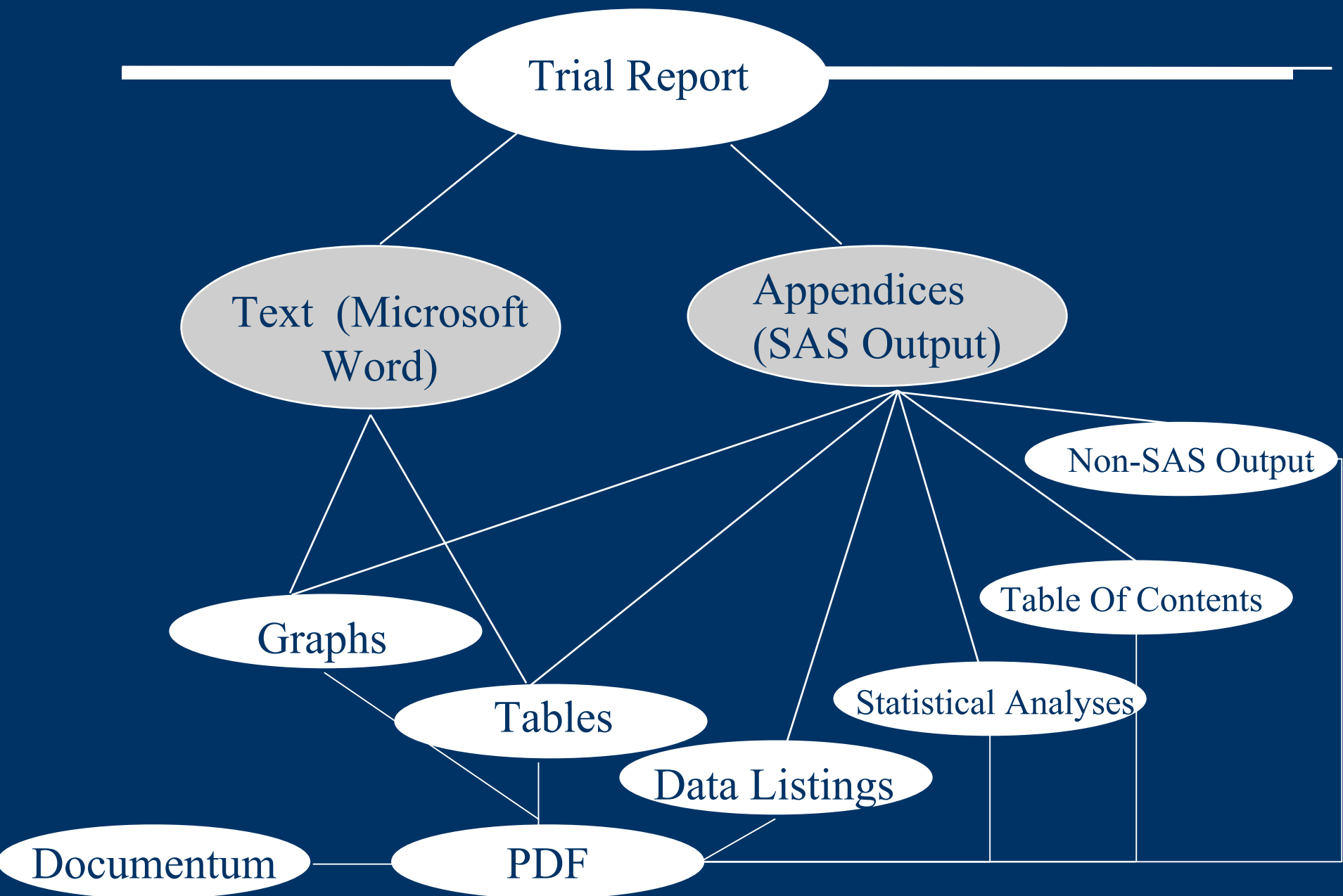
ABCD











Problems (Initial System)

- Page Numbering and Layout
 - Margins
 - Portrait Header on Landscape Page
 - Report Identifiers
- Numbering
 - Page Numbers With Prefix
 - Landscape Title and Footnote
 - Graphs Interspersed With Tables, etc.
- Titles and Footnotes
 - Portrait Title - Contains the Appendix Number and the Number of the Data Display
 - Landscape Title - Contains the Number and Description of the Data Display
 - Footnote - Contains the Program Name, Date Run and Source Data

Solution (Initial System)

- SAS/Graph Device Drivers
 - Include Graphs in SAS Appendices and Word Text
- 'SAS-Tab-to-Word' Macro
 - Include SAS Tables Into Word Text
 - Now replaced in SAS V.8 by ODS
- Postscript Code
 - Margins
 - Portrait Header on Landscape Page
- Meta file (SAS Dataset)
 - Contains Information About Each Data Display
 - Titles and Footnotes
 - Selection, Ordering and Numbering of Displays

The Solution (Continued)

- SAS Macro Facility and SAS Data Step
 - Page Numbers With Prefix
- 'Partially Controlled' Link between O*C and Documentum
 - Access to O*C data
 - Output to Documentum

- Automated Procedure
 - Integrate ASCII and SAS/Graph Catalogs Into One Document
 - Keep Track of Which SAS Program was Used to Produce Each Display
 - Add or Remove Displays From the Appendices
 - Renumber Displays

What the Person Using PM Does

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- Enter Information About Each Data Display in the PM 'Meta' SAS Data set - can use Drag and Drop to structure report
- Write SAS Programs to Produce the Data Displays
- Include

```
%let proiname=xxxxxxx.sas;  
%let titles;
```

at the beginning of each program

What PM Does to Produce Appendices

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- Run SAS Reporting Programs
- Save Outputs as SAS Catalog Entries
- Sort Pages Into Correct Order for Report
- Assign Page Numbers
- Create a Portrait Header
- Create a Table of Contents
- Print and/or Save an Electronic Copy
- Create Documentum specific version (PDF)

New Version (Improvements)

- Cut and Paste facilities from Word
- Import from Excel option for Meta file
- Change Control
 - once program run in RAGe or imported then Change Control is present
 - Three Levels
 - Change Control
 - Change Control and Restricted Access
 - Change Control / Restricted Access / Validation
- 21 CFR Part 11 Compliance !!

- 21 CFR Part 11 Compliance !!
 - Is this an improvement?
 - Sign-off (one part of two part signature) after:-
 - Program Edit
 - Running Program (e.g. Creating Output)
 - Printing Output (Hardcopy report)

What Have we Achieved?

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-
- A Consistent Layout and Format for Every Page of the Report
 - Report Appendices can be Produced With a few Mouse Clicks
 - Documentation is Produced Automatically - aids in Validation
 - Table of Contents is Produced in SAS Automatically
 - Soft scanning converts PS to .TIF / .PDF
 - Controlled Program Environment
 - Regulatory Support

What Have we Achieved?

- Standardisation
 - Method for Producing Reports
 - Storage Location of the Programs and SAS Outputs and Logs
- Change Control
- 21 CFR Part 11 Compliance
- DEMO