
DataFax Experience from a Large International, Multi-Centre Trial: The HOPE Study

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Overview of Study

- Study to examine cardiovascular outcomes in high risk group
- 2x2 factorial design, an ACE-I and vitamin E
- 9541 patients for a mean of 4.5 years
- Follow-up every six months
- 267 centres, 19 countries
- Coordinated at McMaster University in Hamilton
- Government/industry funding

Considerations

- **PO Considerations**
 - » First study run by the group
 - » Setting up toll free connections
 - » Investigator held IND
- **Regional Variations**
 - » Different Start-up Dates
 - » Telephone lines
 - » Usual methods of data collection
- **Centre Considerations**
 - » New to clinical research
 - » Dedicated staff
 - » Comfort with fax machine
 - » Long term follow-up
 - » Re-imburement (based on receipt of clean forms)

Considerations

- **Sponsor**
 - » Monitoring
- **Study stopped 7 months early because of clear benefit**
 - » Investigators informed in April 1999, majority of pt visits completed by June 30th
 - » Main results have been published in NEJM
 - » Regulatory submission made in US
 - » Canadian and European submissions in ~ 3 wks

What May Effect Data Quality

Region

- » Language
- » Past experience

Centre

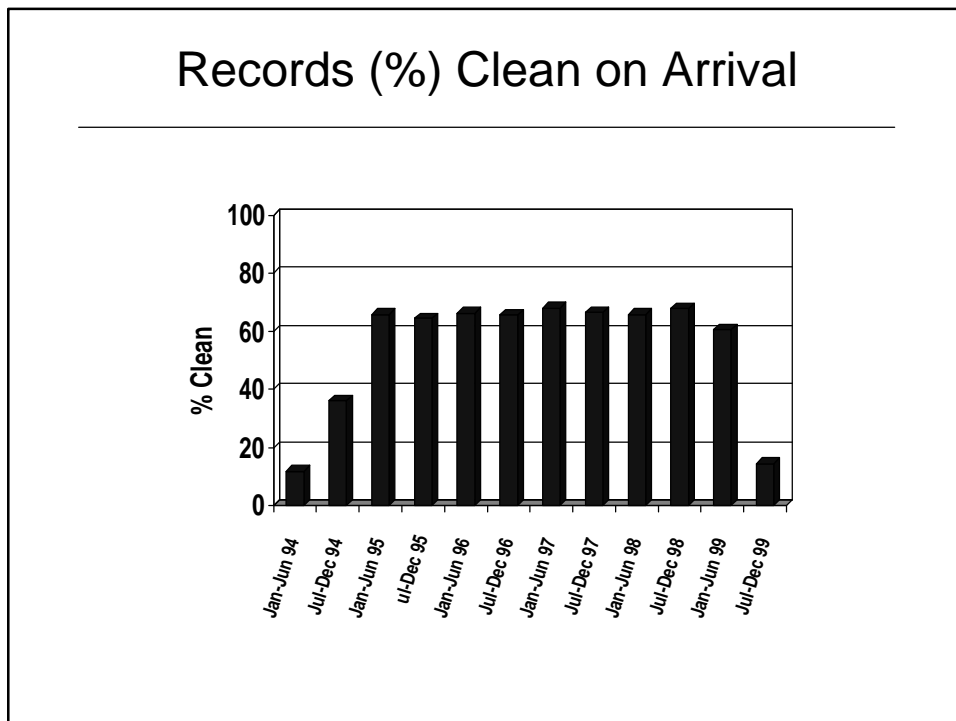
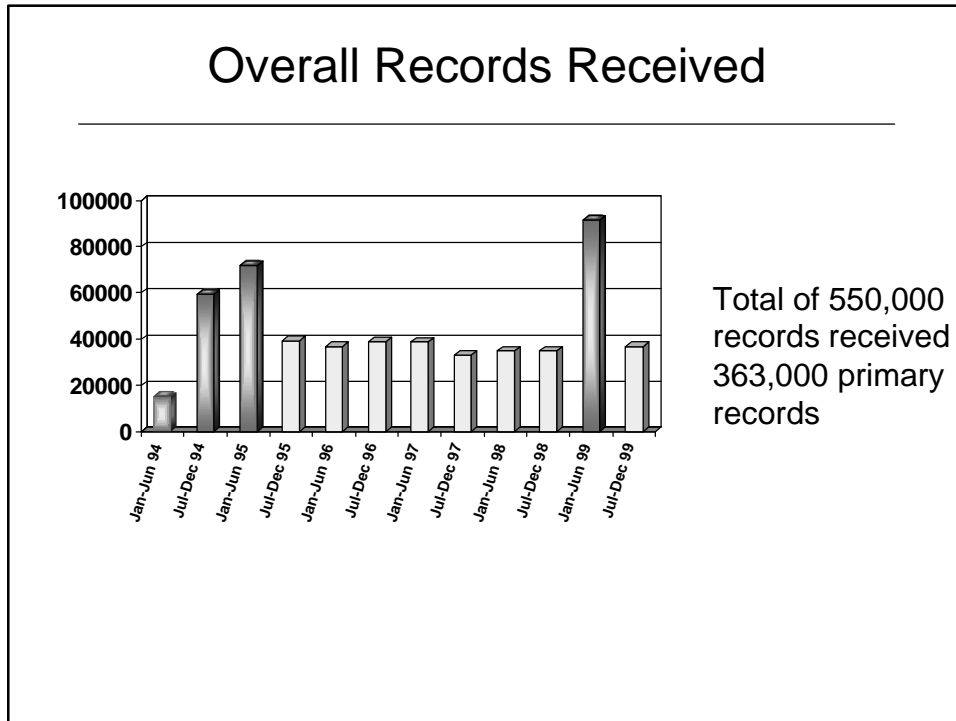
- » Dedicated staff
- » Varying demands of study (i.e. recruitment vs follow-up)
- » Number of patients recruited

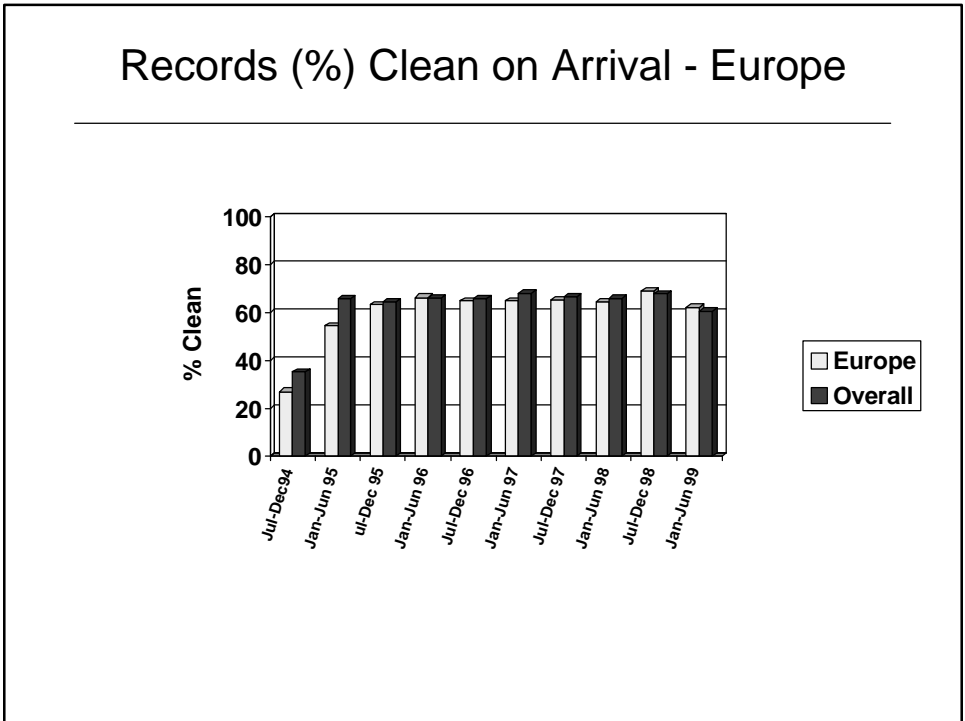
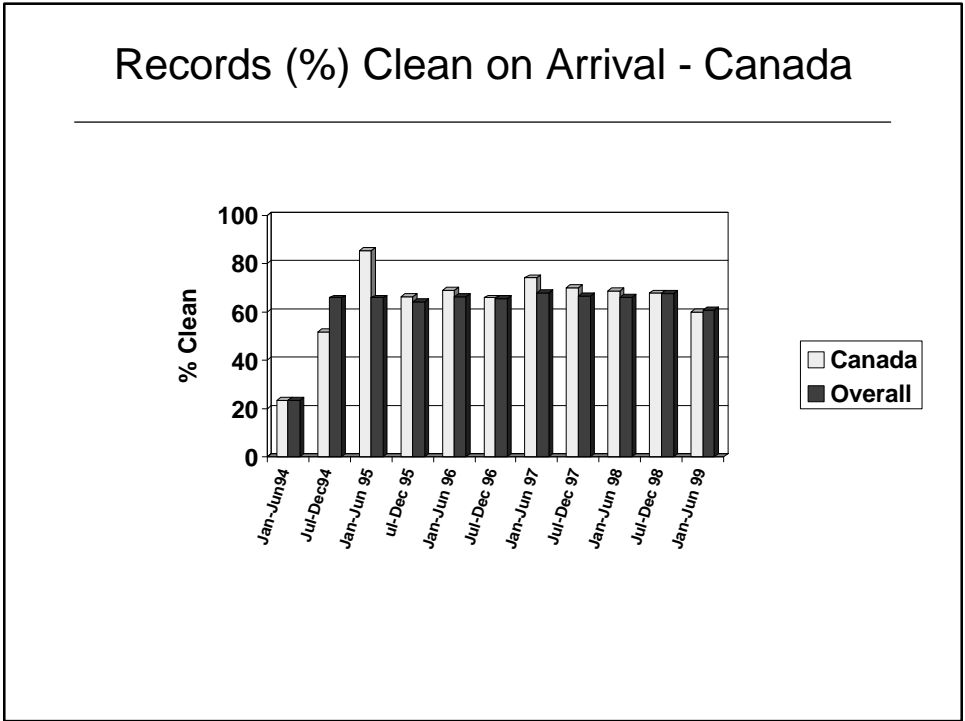
Project Office

- » Case report form design
- » Clarity of QCs
- » Monitoring

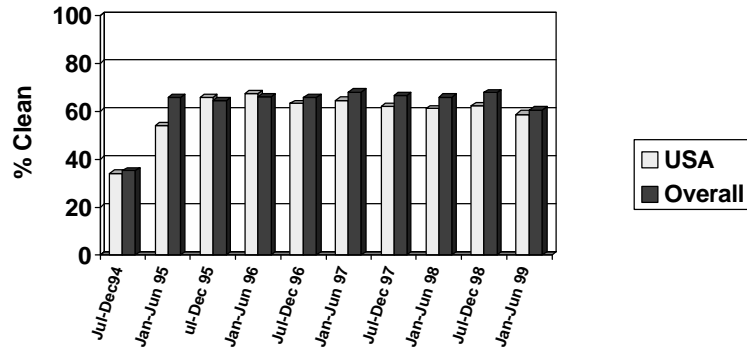
DataFax Outcomes

- % Clean on Arrival
- Time from Visit to QC Resolution
- Number of QCs
- Time from QC Notification to Resolution

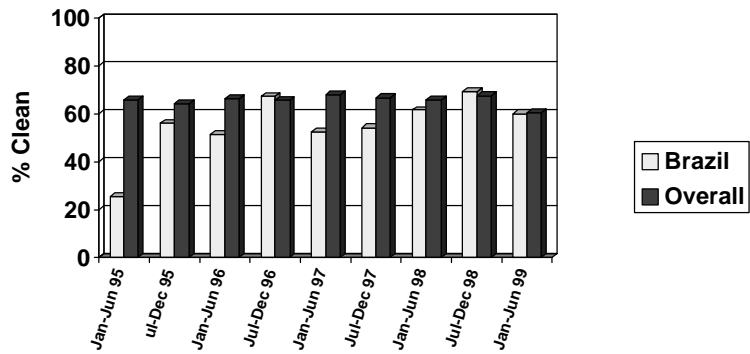




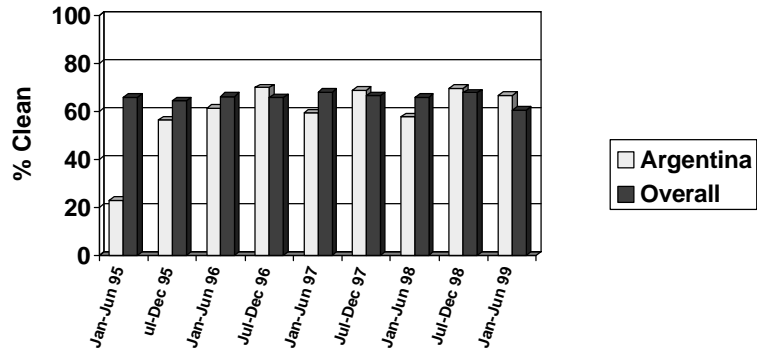
Records (%) Clean on Arrival - USA



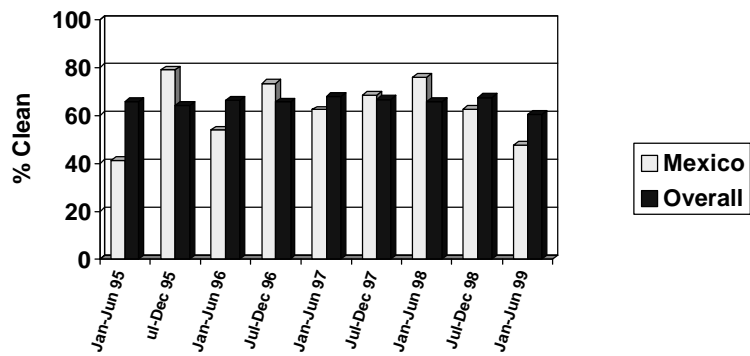
Records (%) Clean on Arrival - Brazil

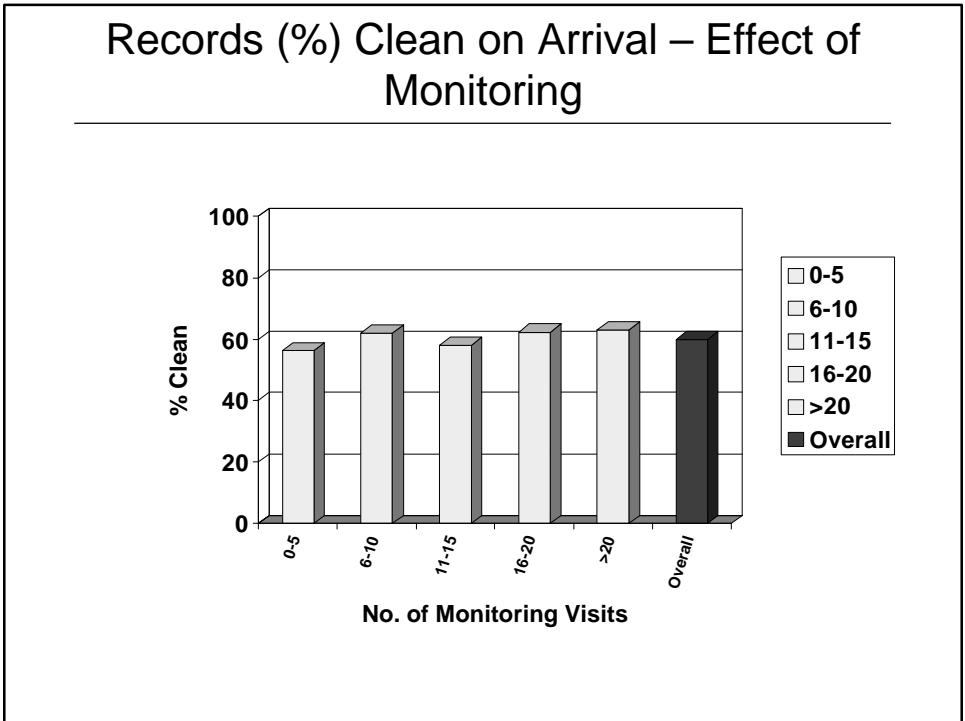
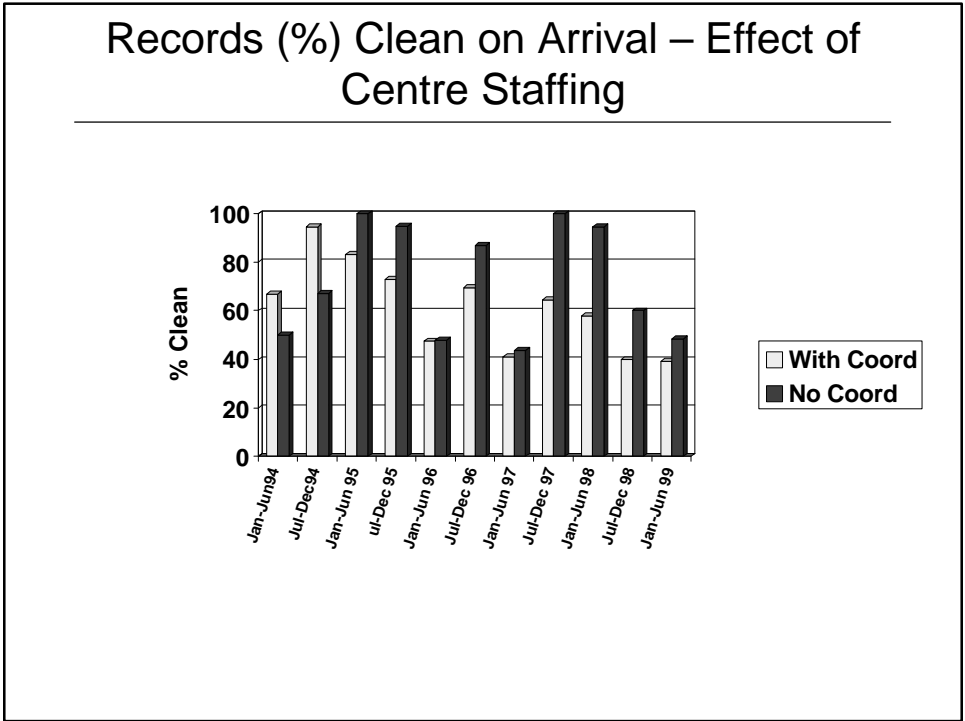


Records (%) Clean on Arrival - Argentina

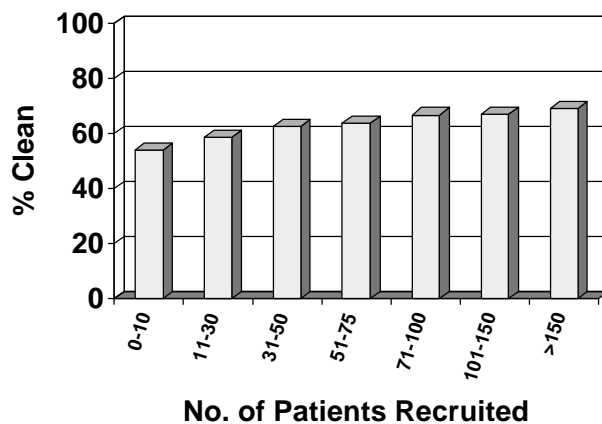


Records (%) Clean on Arrival - Mexico





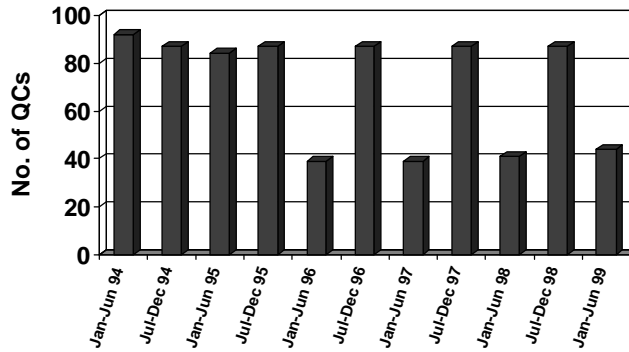
Records (%) Clean on Arrival – Effect of Number of Patients Recruited



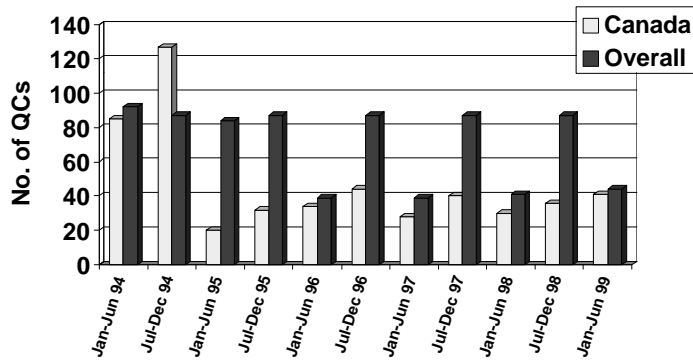
Factors Effecting %Clean on Arrival

- **Neutral**
 - » Case Report Form Design
 - » Monitoring
- **Positive/Negative Influences**
 - » Regional variations
 - » Centre Staffing
 - » Number of Patients Recruited

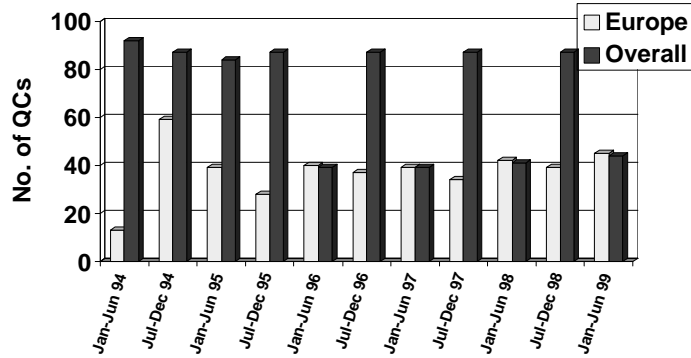
Number of Quality Control Issues Per 100 Records - Overall



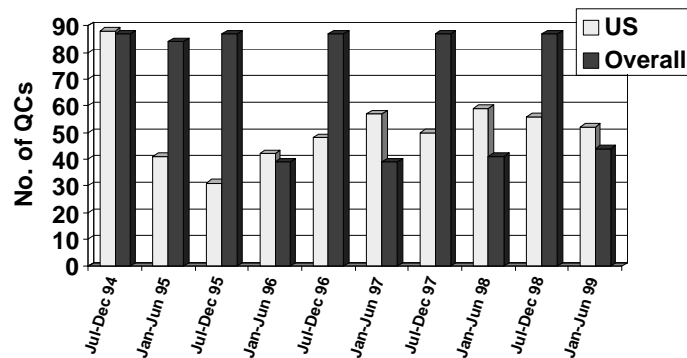
Number of Quality Control Issues Per 100 Records - Canada



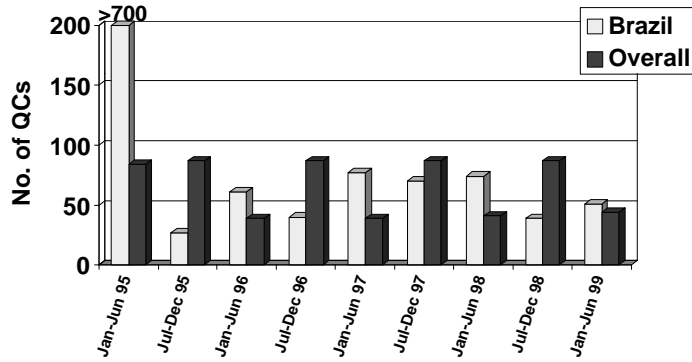
Number of Quality Control Issues Per 100 Records - Europe



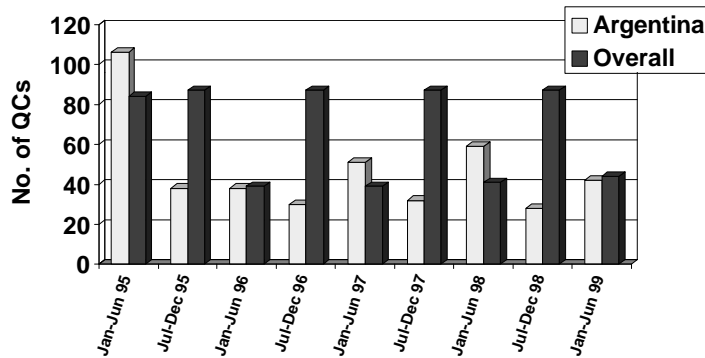
Number of Quality Control Issues Per 100 Records - US

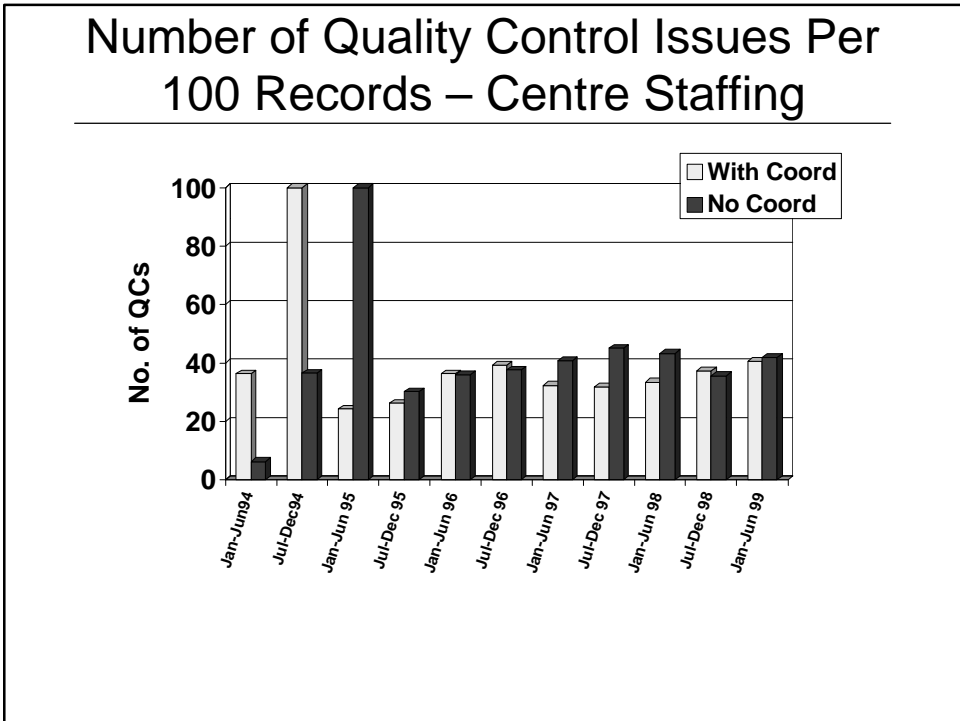
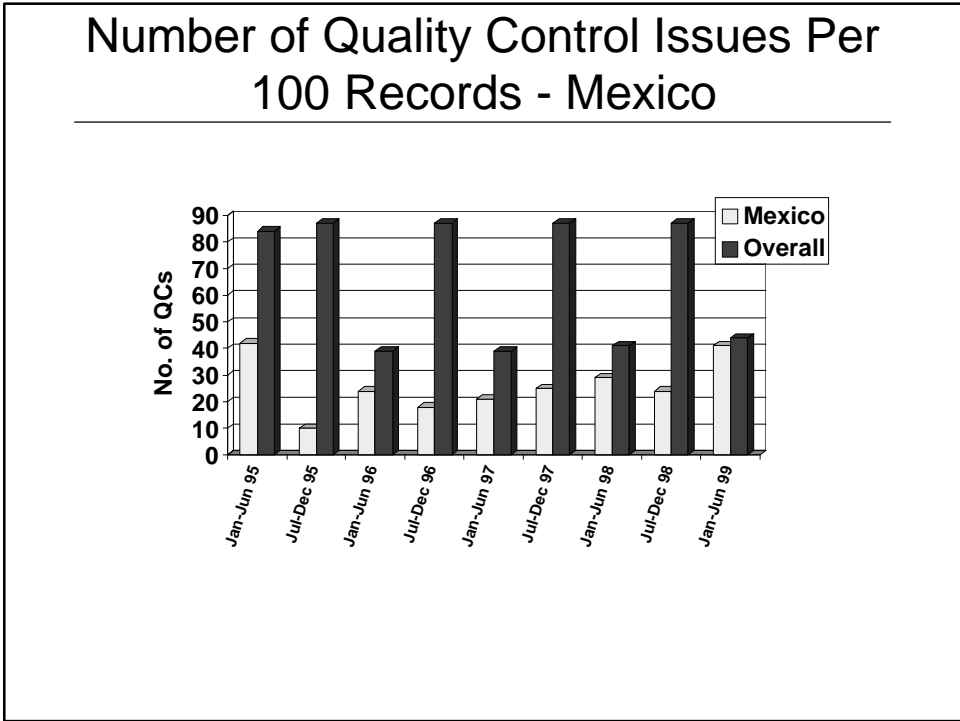


Number of Quality Control Issues Per 100 Records - Brazil

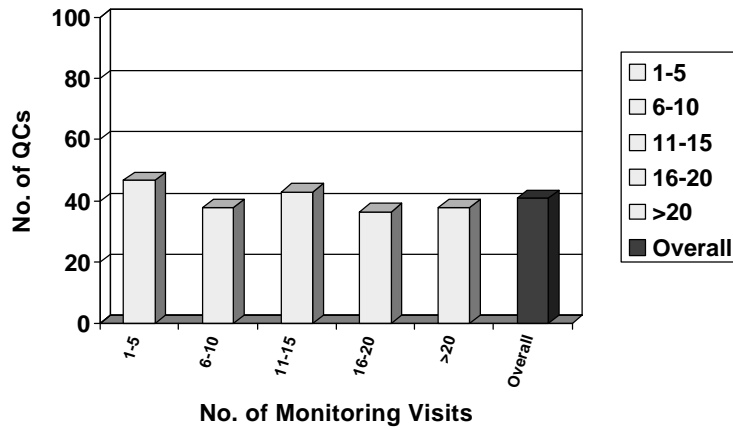


Number of Quality Control Issues Per 100 Records - Argentina



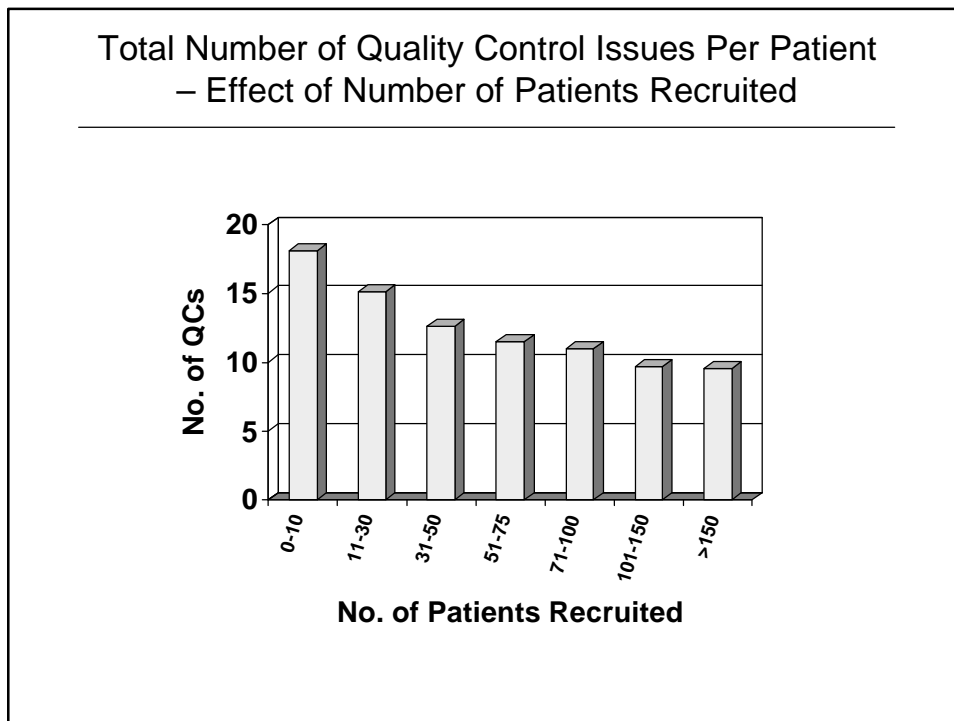
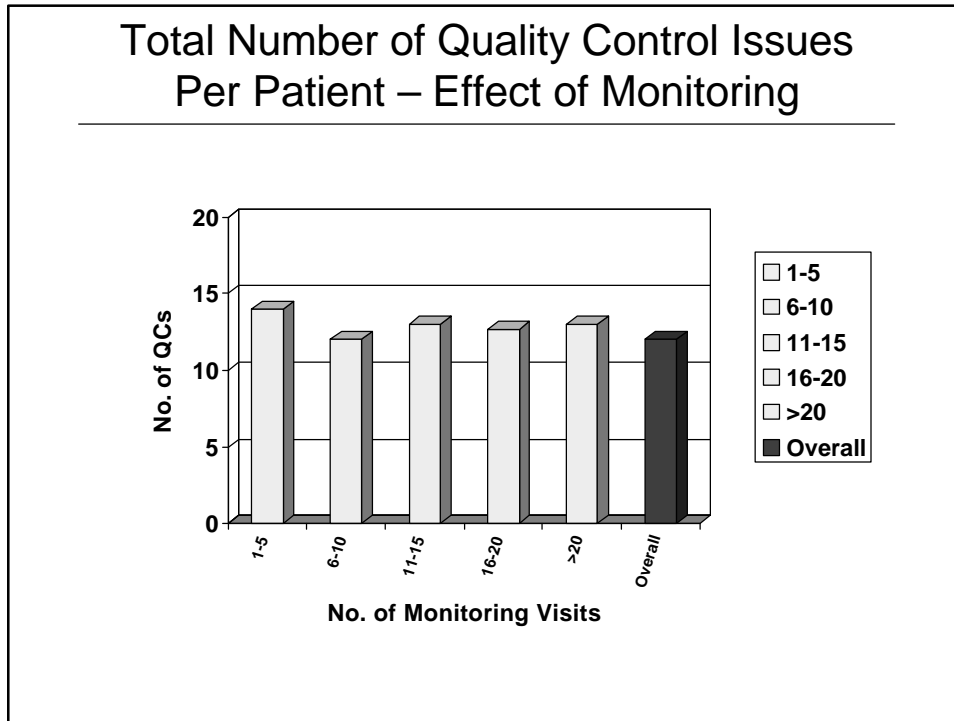


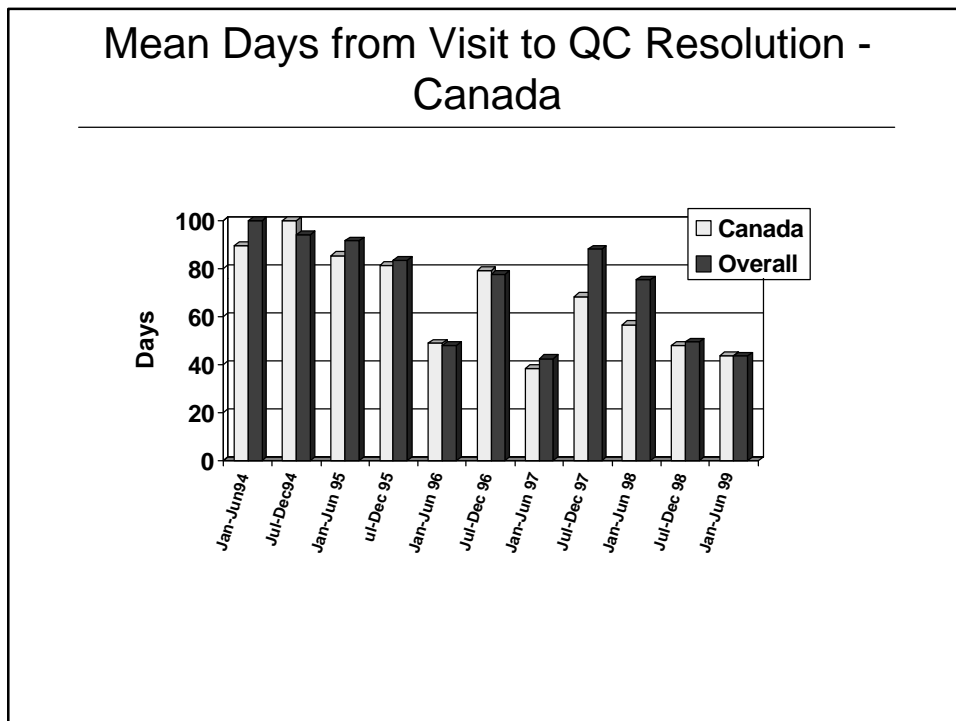
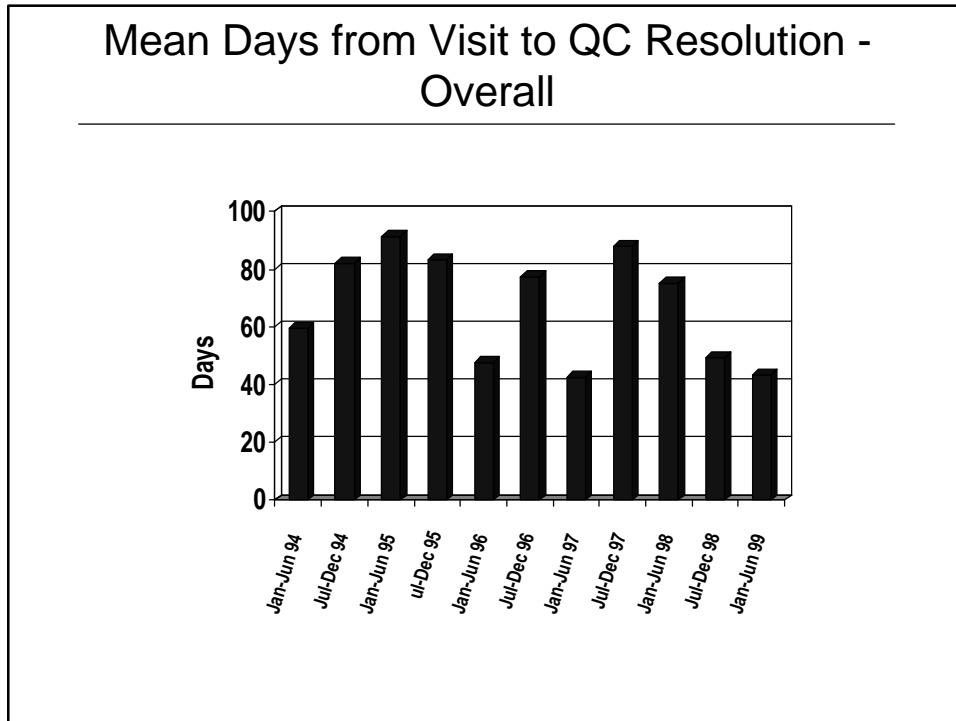
Number of Quality Control Issues Per 100 Records – Effect of Monitoring

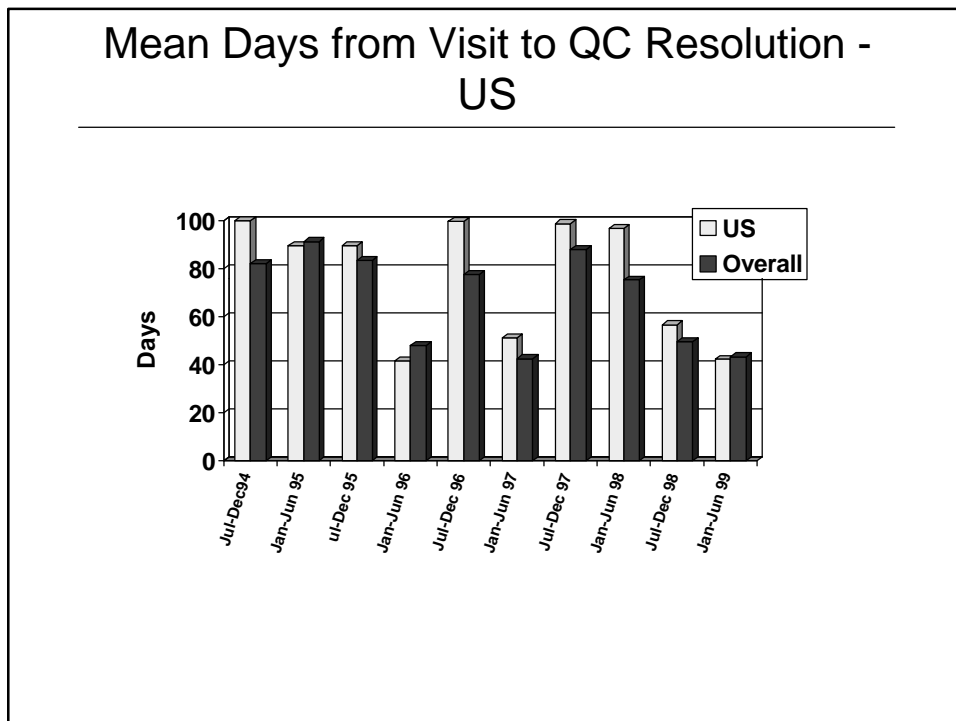
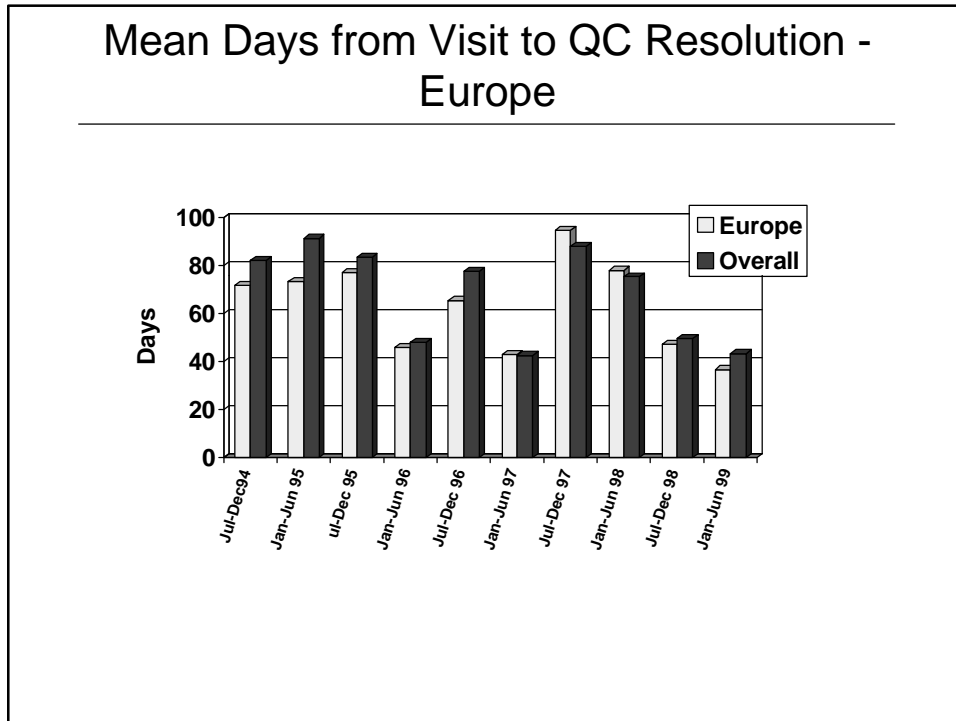


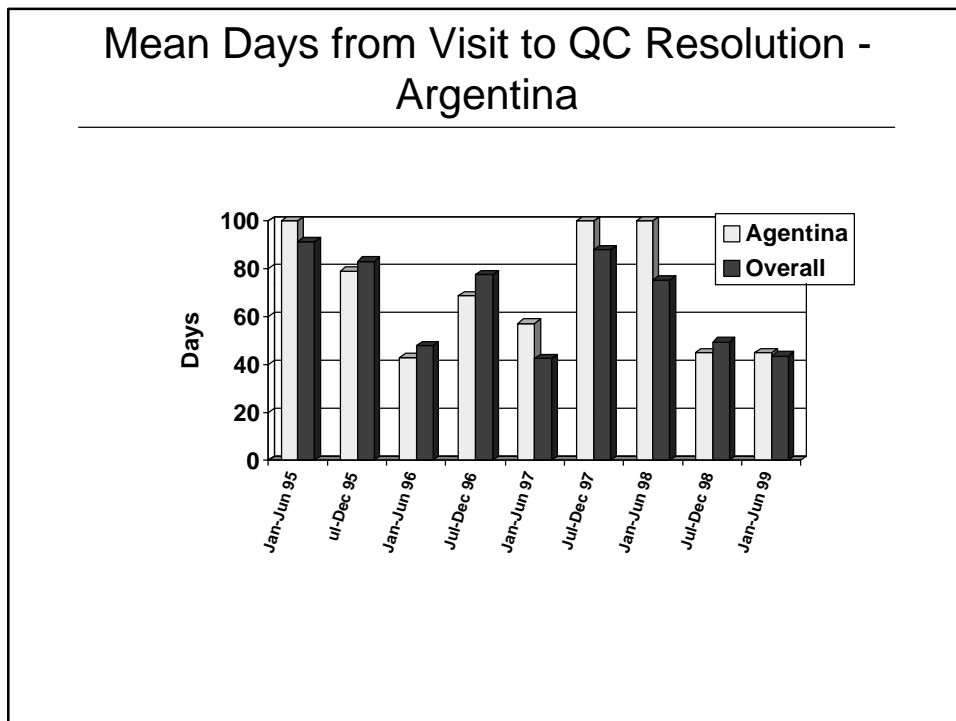
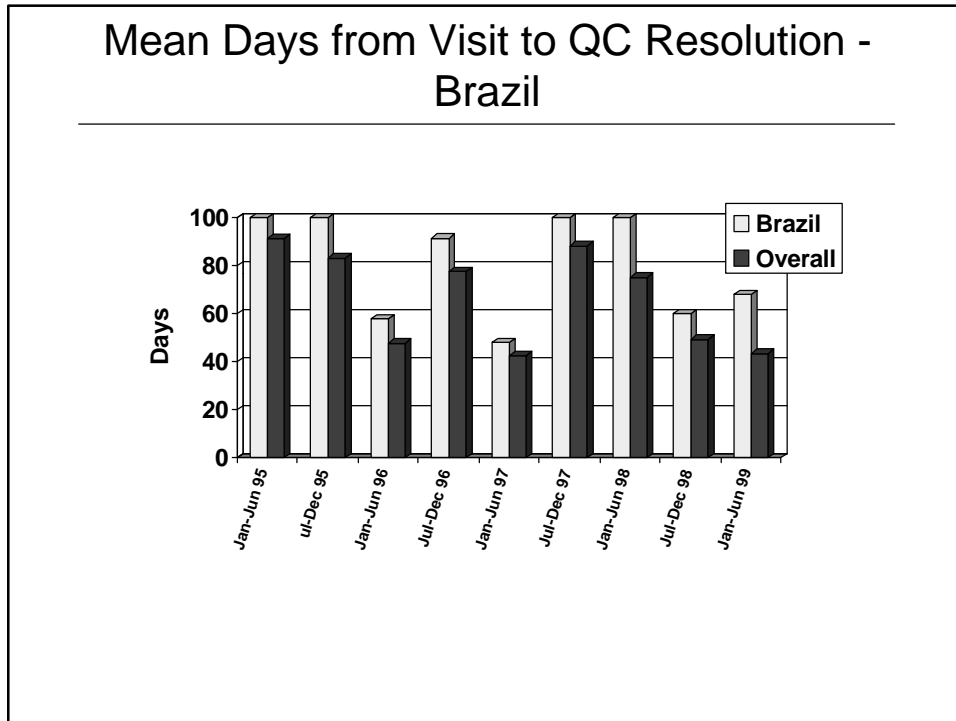
Number of Quality Control Issues Per 100 Records – Effect of Number of Patients Recruited

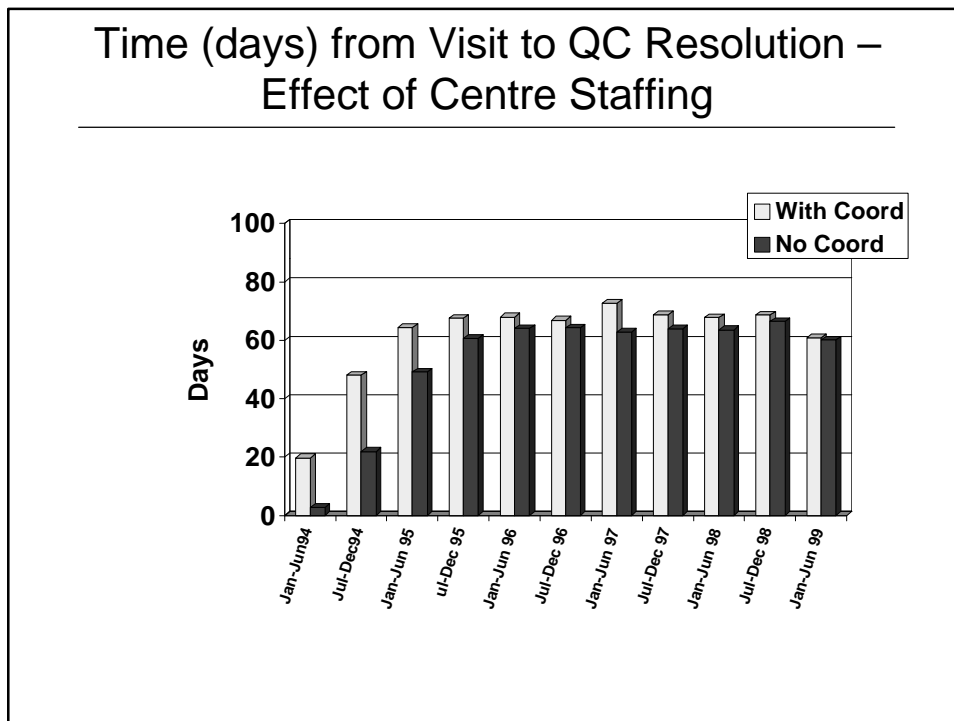
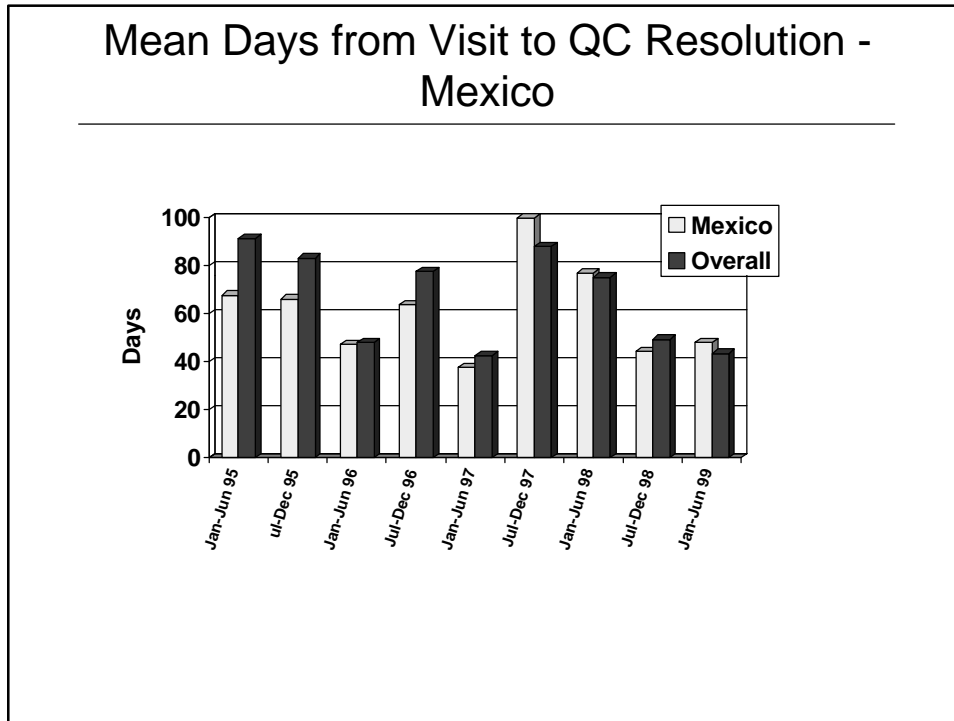


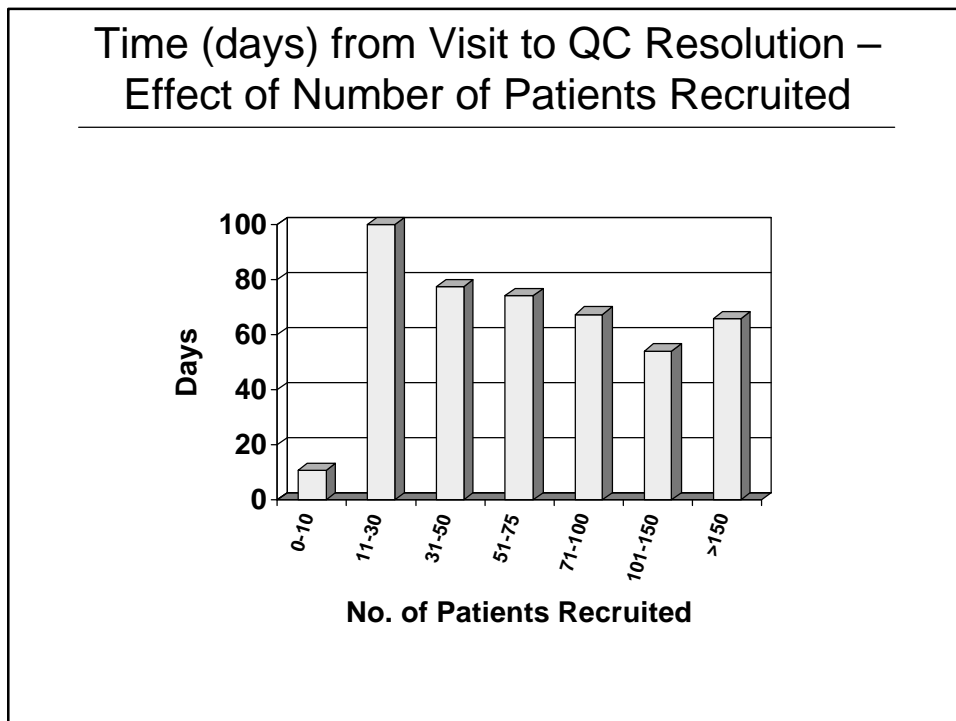
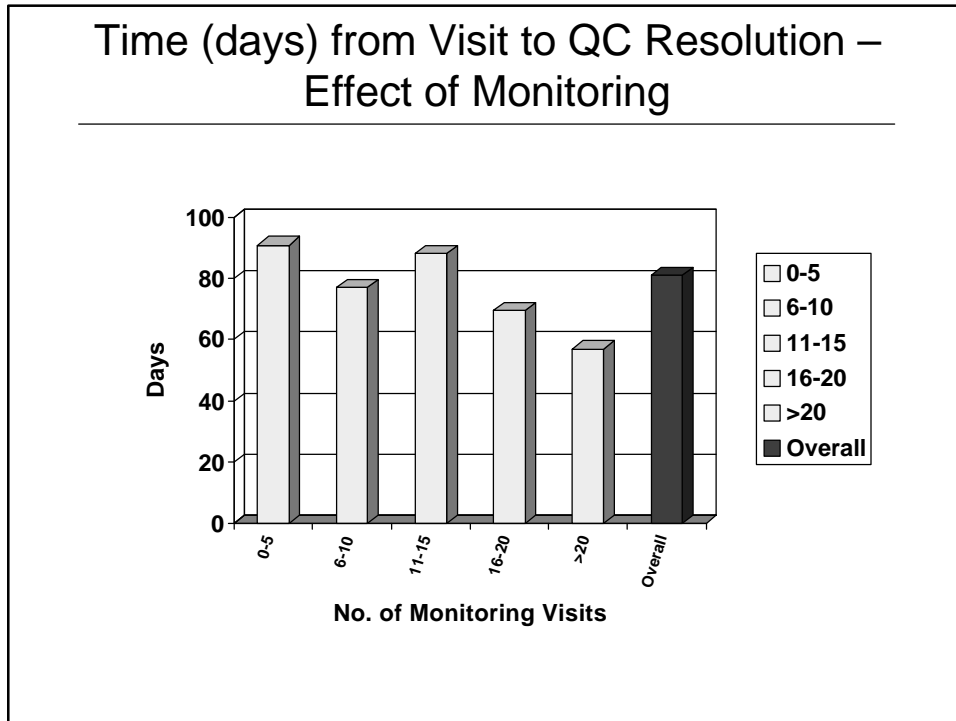


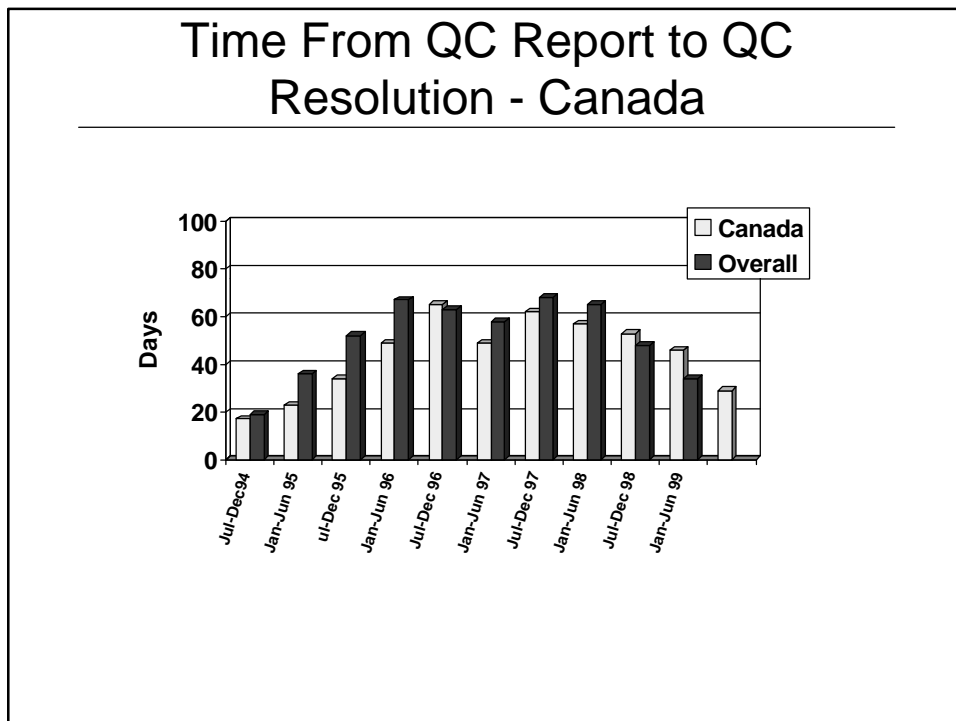
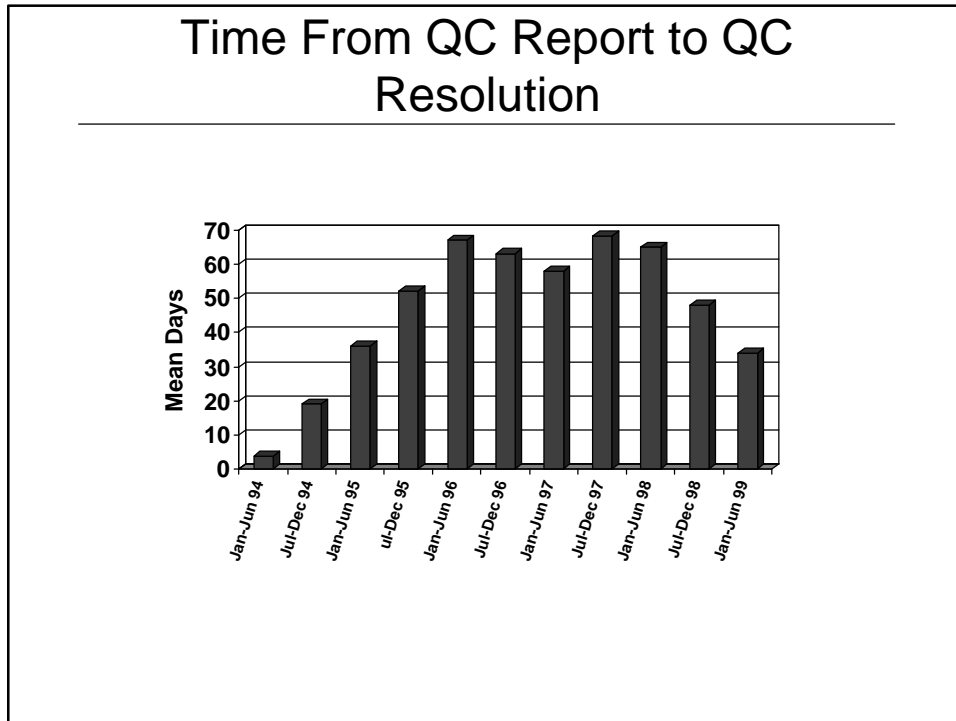


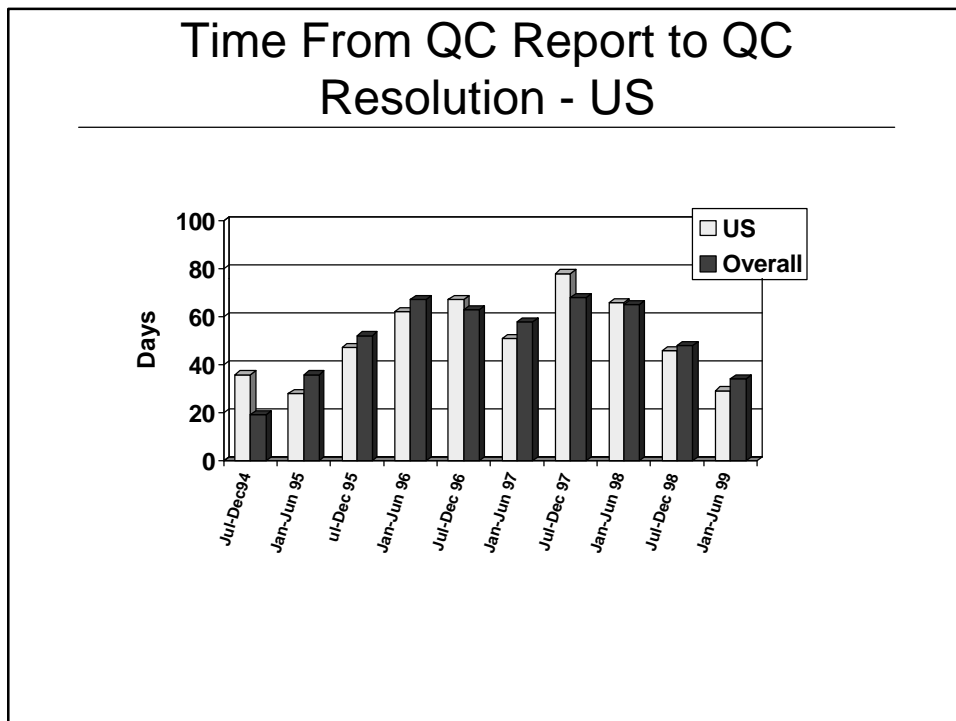
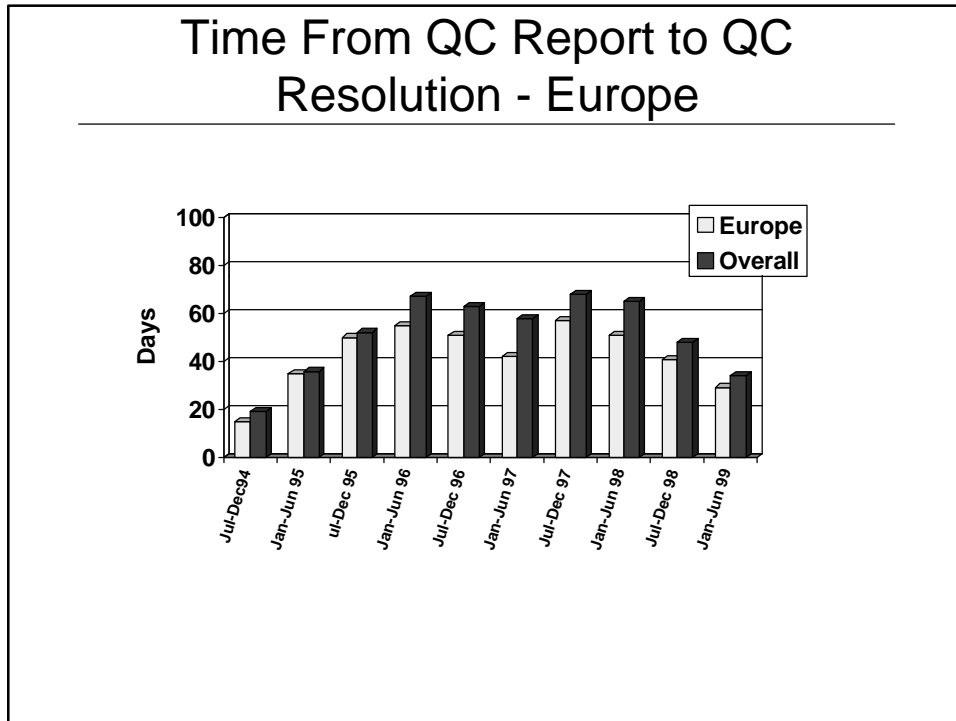


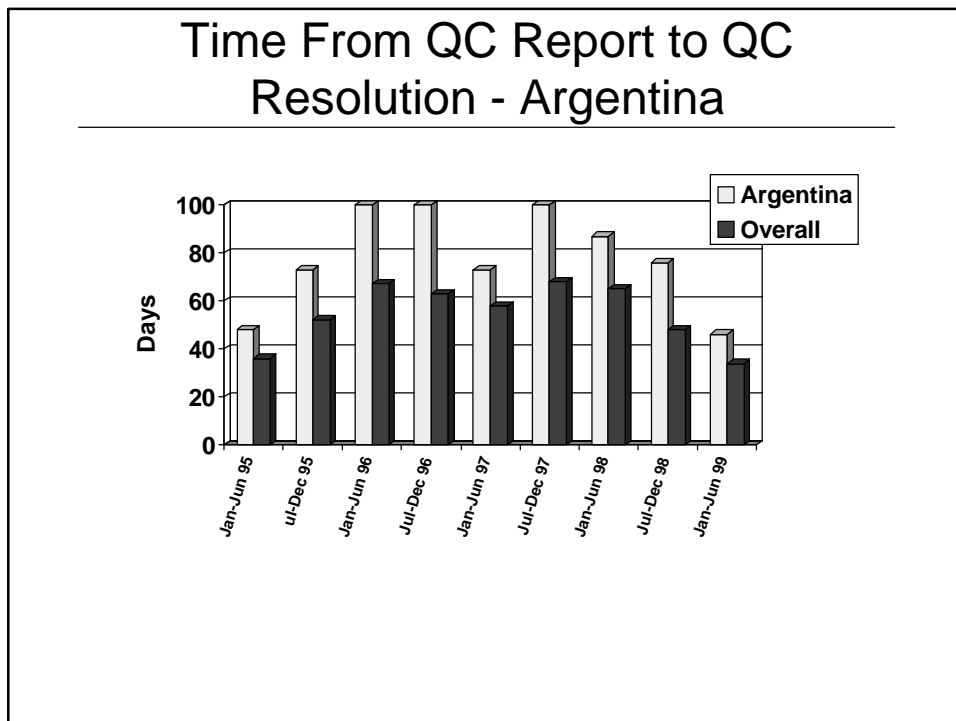
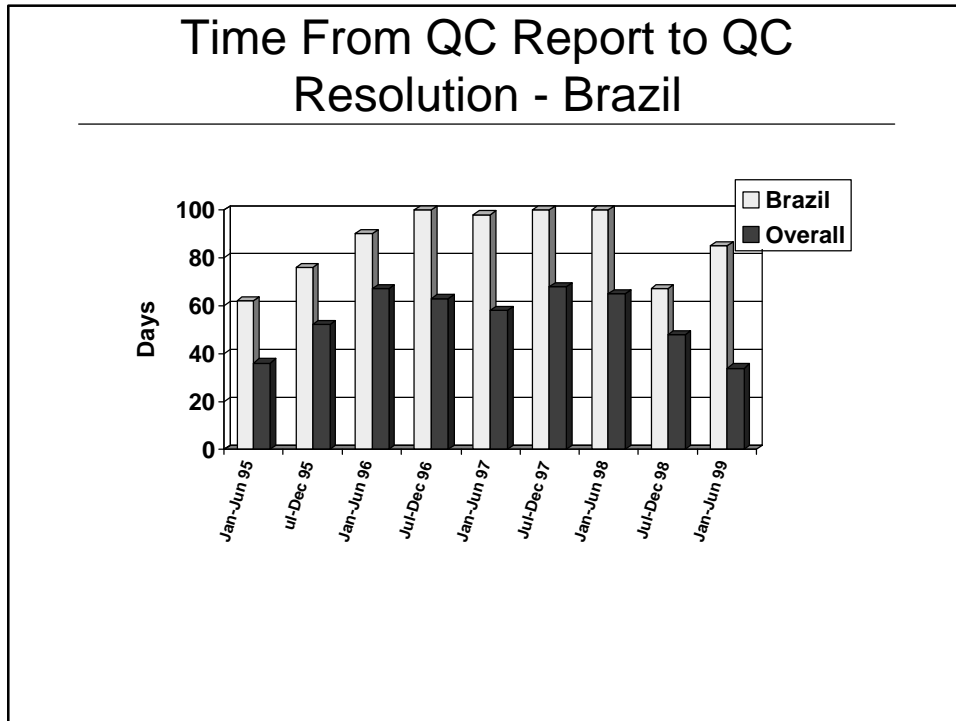


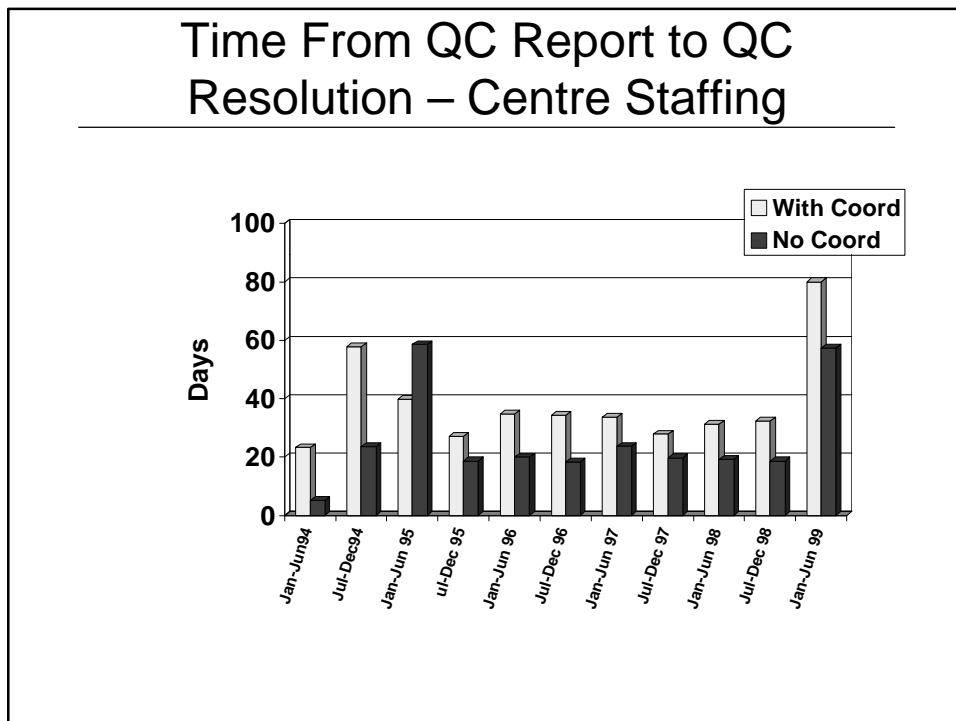
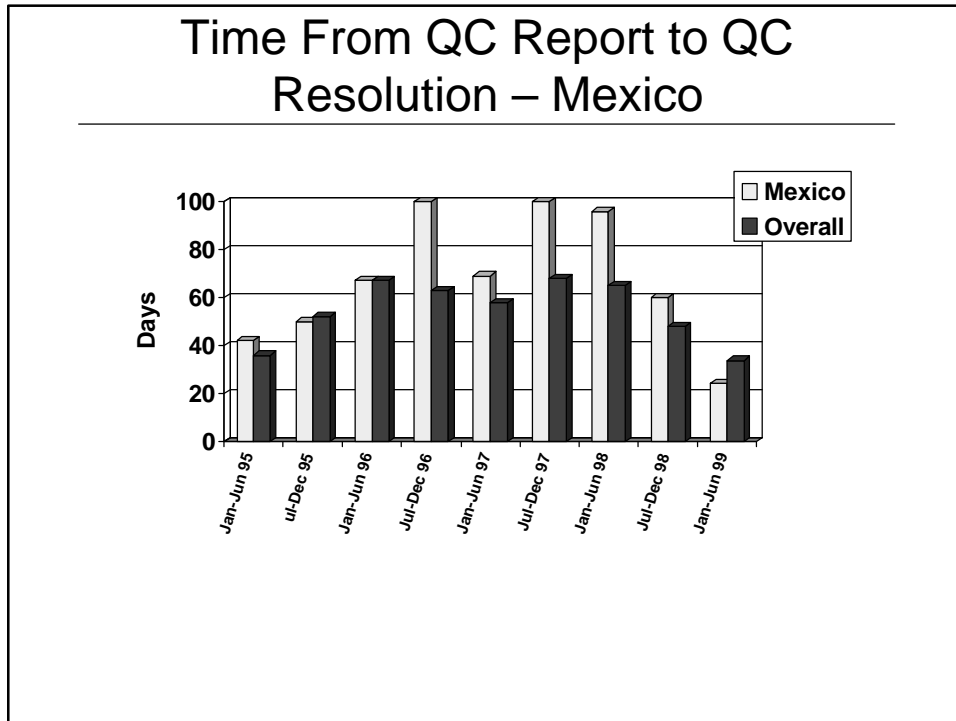




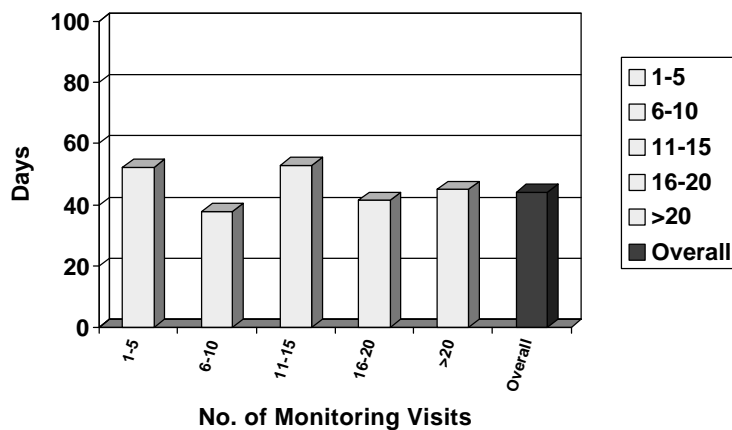




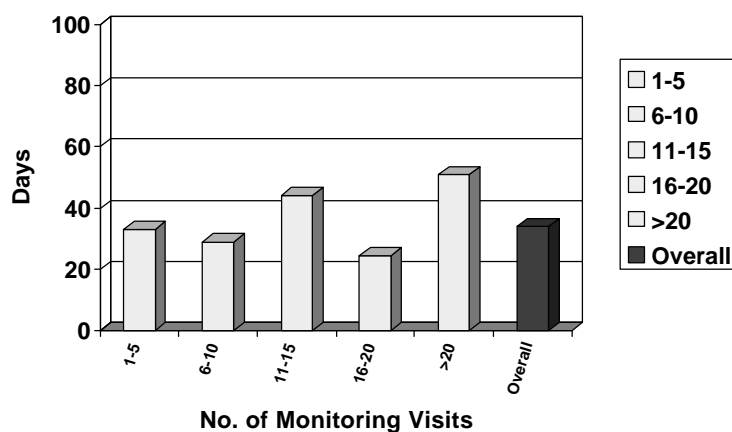




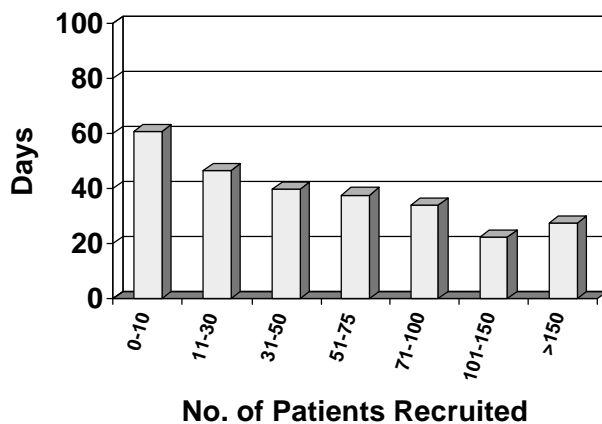
Time From QC Report to QC Resolution – Effect of Monitoring



Time From QC Report to QC Resolution – Effect of Monitoring at Study End



Time From QC Report to QC Resolution – Number of Patients Recruited



Summary

- **Regional**
 - » Variations in Data Quality/QC Resolution
- **Centre**
 - » Staffing not as important as level of commitment
 - » Increased workload resulted in better data quality
- **Project Office**
 - » Case report form improvement had little effect
 - » Monitoring was not preventive, but may decrease time to resolve QC notes at “problem” centres
 - » Payment schedule did not influence data quality, but meeting attendance may have