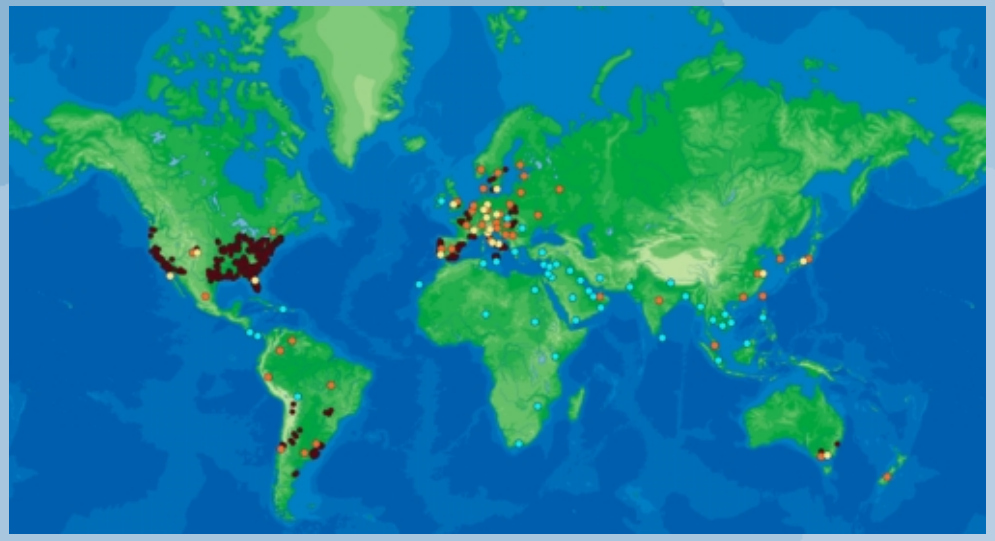


GAMBRO®

A Leading Global Medical Technology and Healthcare Company

Gambro

Gambro Renal Products

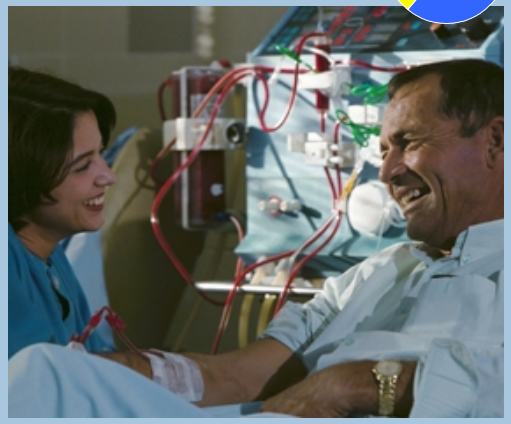
Products and systems for renal care

32%

Gambro Healthcare

Managing and giving care to 51.000 renal patients in 675 clinics

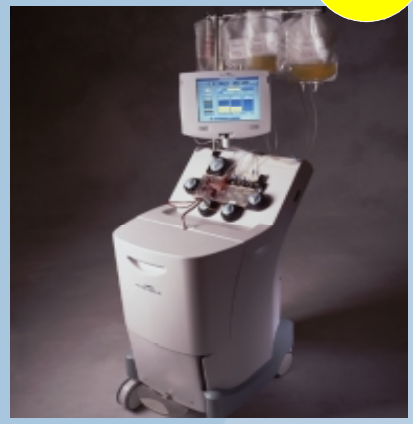
61%



Gambro BCT

Products and systems for separation/ thera-peutic use of blood components and cells

7%



% of revenue 2001

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CA group?

- We are part of GRP, in charge of pre-market studies aiming to support CE marking or MRP
- We are continuously updating our tools
  - ✓ to increase quality of our studies
  - ✓ to be compliant with regulation evolutions
- Today our concern is the data management

Data management?

- From beginning we were working with an in-house Access database. With development of regulations and increased complexity of our clinical study design, this tool needed to be updated.
- New specifications demonstrate that instead of an update of the actual data base, a complete new system was needed.

Specifications?

- Compliant with regulation
- Easy to train
- Easy to use (no IT support within CA group)
- Should allow data entry and data output
- Should address everybody within CA group
  - Data team to create studies and enter data
  - Monitor and project team to view the data
  - Clinical study director to have tables and graphs for report
- Should ensure data confidentiality as plan to be shared with other Gambro groups
- Easy to update
- Support from supplier

GAMBRO

Pheed-It

- Compliant with regulation:
  - Based on SAS Audit trail tool, etc.
- Easy to train:
  - Training material and online help
  - 1 day presentation and 1 day training was OK for data team to start working in test environment
- Easy to use:
  - Summary of important features (as DVM status, proof-reading, study performance, etc) allowing to follow across time study data management implementation

Pheed-It

- Data entry and data output:
  - Data entry could be done from Gambro offices worldwide using the Intranet or at study site or from a CRO office using remote access
  - A report engine allow easy access to usual graphs and tables for the project team
- Security as all types of users:
  - Access permissions to the different functionality to secure Metadata: System-Adm, Super CDM-ADM, CDM-ADM, CDM, DE, Monitor
- Confidentiality as all data in the same base
  - Study access definition, to give data access permissions only to the ones attending to the project within the Gambro project group

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- Easy to update:
  - Changes done on Gambro request could be done within 2-3 weeks.
  - All modifications linked to project specifications are done within 2-5 days

- Support from provider:
  - Hot line
  - Real partnership during all the implementation phase
  - Great availability from the Pheed-It team

Implementation?

- PheedIt installed - January 2002
- PheedIt training - January 2002
- Gambro training in test environment - February 2002
- First pilot study - March 2002
- Report Engine development - April 2002
- First production study - May 2002
- Report Engine validation - June 2002

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Thank You for Your Time!

Catherine Collier
Clinical Affairs
Group Manager

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