QUBAS

BIOASSAY SOFTWARE

— quantics in an app —

What is QuBAS?

QUBAS
BIOASSAY SOFTWARE
— quantics in an app —

❑ User-friendly biostatistical software package

❑ Everything you'd expect…

Logit

Probit

Linear Models

4PL Models

5PL Models

Equivalence Tests

Parallel Line Analysis

Interpolation Analysis

Outlier Management

GMP & 21 CFR Compliant

What is QuBAS?

QUBAS
BIOASSAY SOFTWARE
quantics in an app

- ❑ User-friendly biostatistical software package
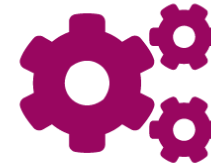- ❑ And **so much more!**

Unrivalled Flexibility

Automatic Data Transfer
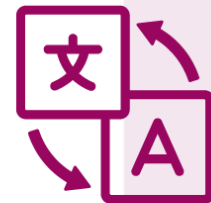
Unlimited Metadata Trending

CrtV™

User-friendly UI

Interactive Development Record

Access anywhere

Language Options

Intuitive Data Views

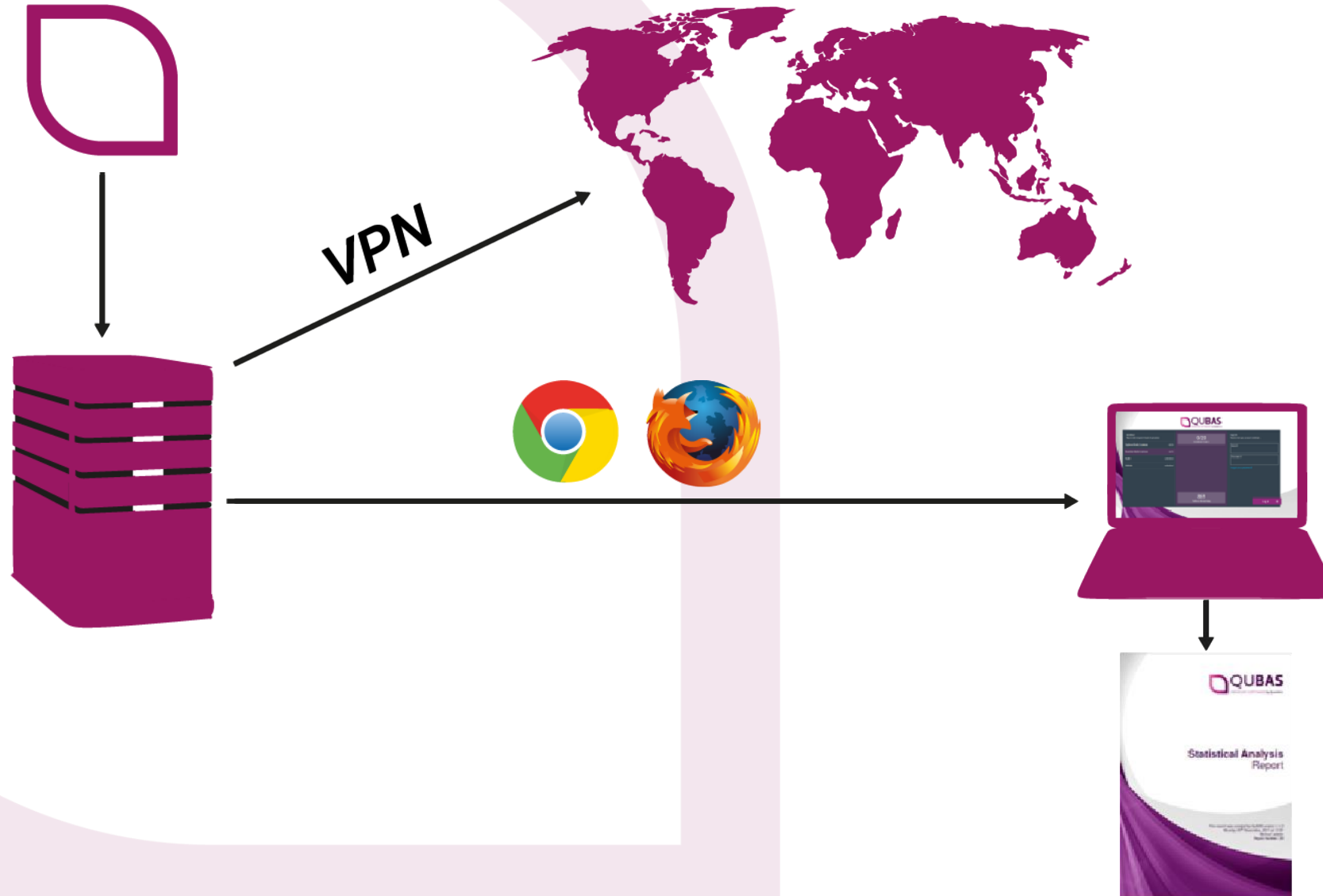Statistical support by Quantics

Regulatory Compliance

- Quantics Biostatistics – bioassay consultancy for more then 20 years
- Director of Statistics sits on USP

- Membership Schemes
  - GLP (7 Years)
  - ISO9001:2015 (11 Years)
- Other Schemes
  - GCP
  - GMP
  - 21 CFR pt11
  - ICH

Accessing QuBAS

Or...

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BIOASSAY SOFTWARE
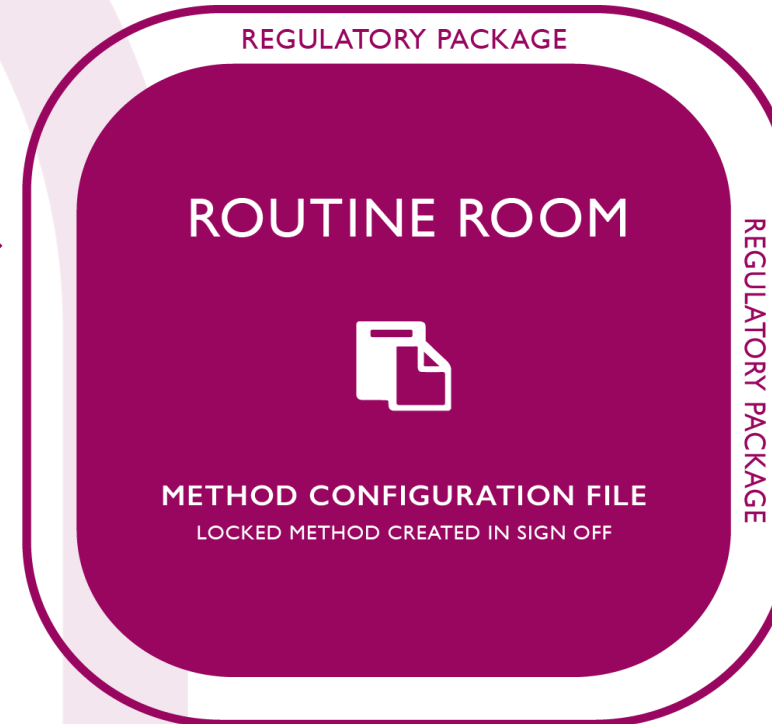— quantics in an app —

QUBAS
CLOUD

QuBAS Modes

Development Room

ONCE YOU INPUT DATA, YOU CAN DESIGN AND RE-DESIGN YOUR METHOD IN THE WAY THAT SUITS YOU BEST, USING ALL OF THE TOOLS QUBAS HAS AVAILABLE.

INPUT DATA

DATA (PLATE MAP) CREATE/EDIT

EXAMINE DATA

EXPLORE/DEFINE ANALYSIS OPTIONS SET SUITABILITY CRITERIA

AUTO SUMMARY WITH EVERY CHANGE

ANALYSE DATA EXAMINE RESULTS

ASSIGN LABELS AT WHATEVER STAGE SUITS YOU

INPUT METADATA AUTOMATICALLY OR MANUALLY

ADD PARAMETERS

Routine Room

REGULATORY PACKAGE

REGULATORY PACKAGE

ROUTINE ROOM

METHOD CONFIGURATION FILE LOCKED METHOD CREATED IN SIGN OFF

2-stage electronic sign-off

Version Control

Final Version

2-stage electronic sign-off

GMP & 21 CFR pt11 Compliant

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Data Input & Plugins

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❏ Import any delimited text file e.g. .csv

❏ Other file formats (e.g. .xml, .xls) can be pre-processed by **plug-ins**

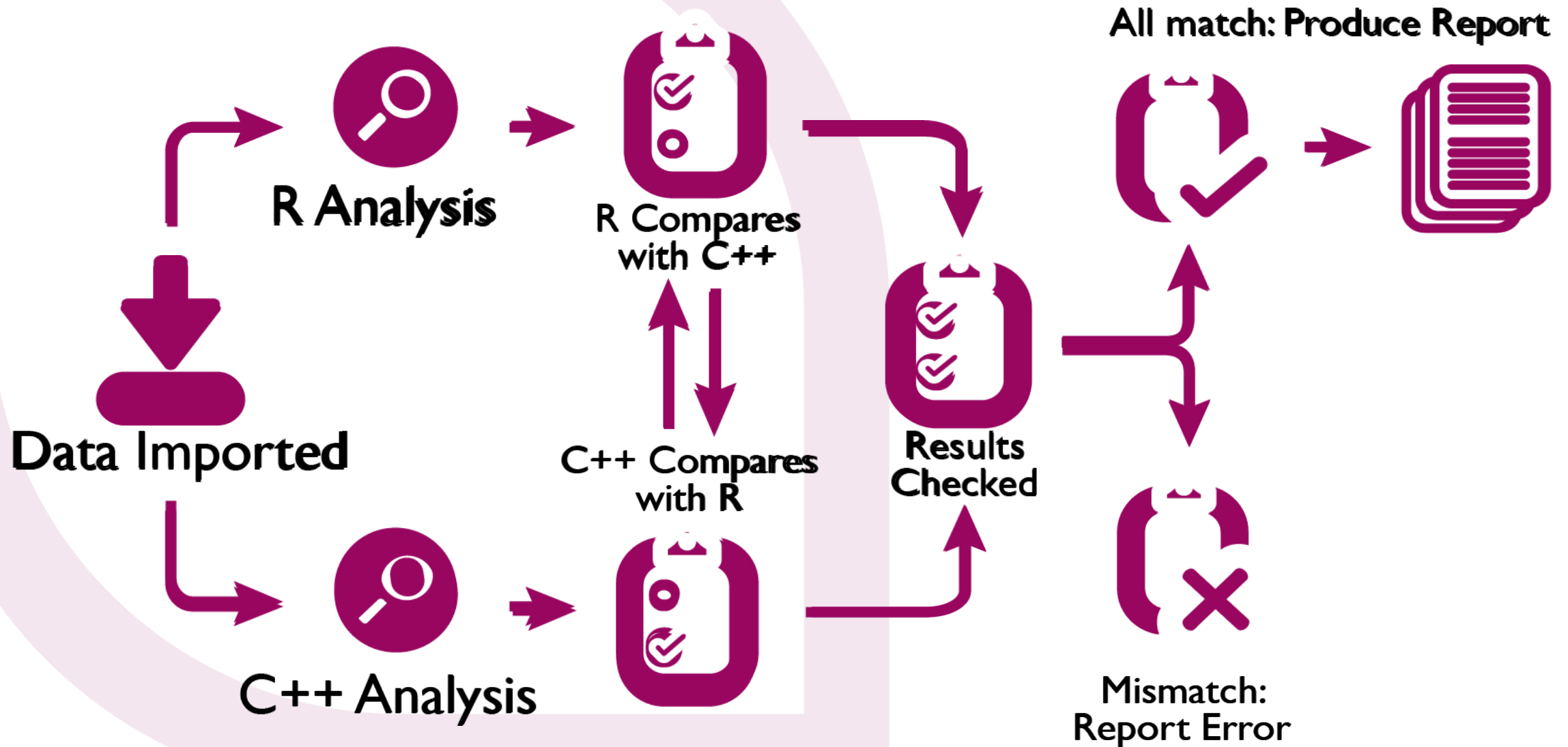❏ Custom plug-ins can be built to suit individual customer needs

Auto-Import/Export
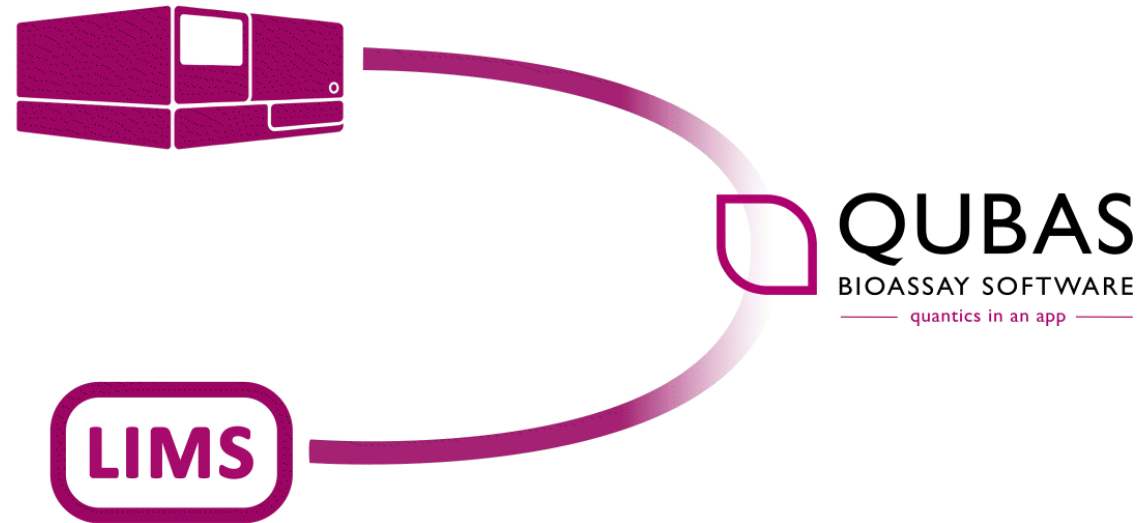
CrtV™

- **C**ontinuous **r**eal **t**ime **V**alidation
- Unique to QuBAS
- Derived from the aerospace industry
  - "Fly-by-wire" aircraft require 100% QC in real time for reliability
  - Use redundant systems and cross-check readings

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CrtV™: Diverse Self Checking Pairs

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R Analysis

R Compares with C++

All match: Produce Report

Data Imported

C++ Compares with R

Results Checked

C++ Analysis

Mismatch: Report Error

CrtV™: Results

Process	Result	Date/time
Validation of installation		
R install check	PASS	26-November-2020 15:33
App install check	PASS	26-November-2020 15:33
Engine install check	PASS	26-November-2020 15:33
Licence check	PASS	26-November-2020 15:33
DSCPP Processes		
input XML validation	PASS	03-December-2020 07:46 UTC
Parsing report ID	PASS	03-December-2020 07:46 UTC
Parsing configuration file	PASS	03-December-2020 07:46 UTC
Parsing statistical model	PASS	03-December-2020 07:46 UTC
Parsing branch B configuration	PASS	03-December-2020 07:46 UTC
Analysis (branch A)	PASS	03-December-2020 07:46 UTC
Output validation for branch A	PASS	03-December-2020 07:46 UTC
Analysis (branch B)	PASS	03-December-2020 07:46 UTC
Output validation for branch B	PASS	03-December-2020 07:46 UTC
Check results from both branches	PASS	03-December-2020 07:46 UTC
Generate report from branch A	PASS	03-December-2020 07:46 UTC
Generate report from branch B	PASS	03-December-2020 07:46 UTC
Check that both reports are identical	PASS	03-December-2020 07:46 UTC

Validation Results

This is a routine analysis: TRUE
Audit trail is complete: PASS
All systems, file operation and analysis validation checks: PASS
Results 100% QC check: PASS
Reports text 100% QC check: PASS

This report is valid for use in GxP systems

Unique Features

❑ All-in-one package

o Supports every stage of bioassay workflow – from development to GMP – as standard

❑ User-friendly and intuitive

o No formulae or programming – less training!

❑ Automatic Metadata Trending

o Use monitoring room to isolate assay parameters and metadata for further investigation