# Pre-clinical biodistribution studies for ATMPs

# Insights from a GLP-certified service provider

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ATMPs include gene and somatic cell therapy medicinal products. For such products, tumorigenesis, chromosomal instability and vertical transmissions in germline cells are potential risks. To address these issues, regulatory agencies worldwide require pre-clinical *ex vivo* biodistribution studies to evaluate the safety and toxicity of e.g. nucleic acid therapeutics. At IMGM, we design quantitative real-time PCR (qPCR) biodistribution studies investigating the persistence of the nucleic acid therapeutic in target tissues, the dissemination into non-target tissues and the expression in germ line cells. These studies are performed Good Laboratory Practice (GLP)-compliantly.

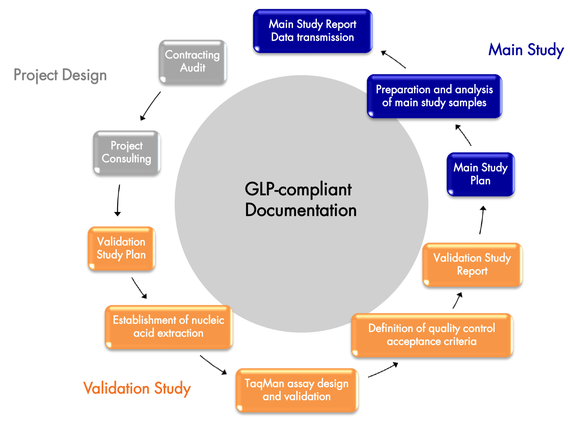
**By selecting IMGM as outsourcing partner for your pre-clinical study, you can count on a professional business relationship.**

- Confidentiality Disclosure Agreements (CDAs)
- Non-Disclosure Agreements (NDAs)
- Frame Service Agreements (FSAs)
- Material Transfer Agreements (MTAs)
- GLP certification
- DAkkS accreditation DIN EN ISO/IEC 17025

## Project Design and Consulting

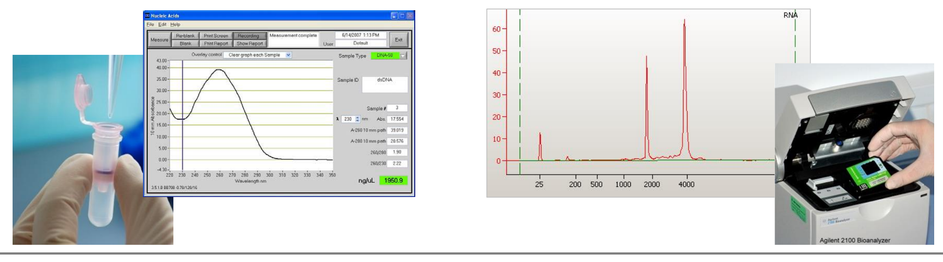
**Consulting and experimental design in close communication between you and your project manager at IMGM will address:**

- Detailed study overview and timeline
- Realistic time frames for experiments, documentation and quality management
- Consideration of licensing authorities requirements
- Number and type of sample sources
- Selection of appropriate reference material
- Best preparation mode for each sample type



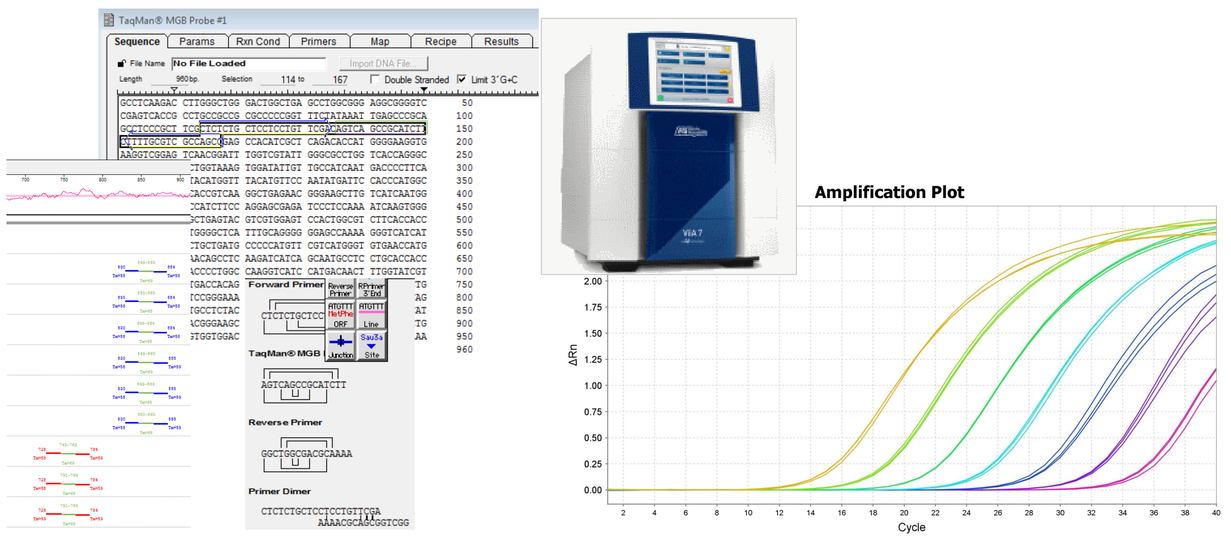

## RNA & DNA extraction

- High quality RNA & DNA extraction
- Minimization of contamination
- Quantification and quality control of each sample



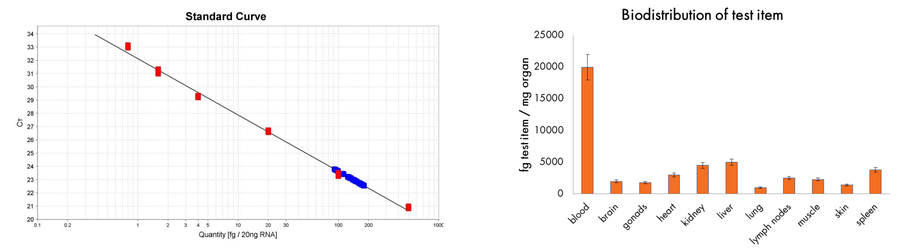

## Validation Study

- Long-standing experience in complex TaqMan qPCR assay design
- GLP-compliant, detailed validation of qPCR assays by defining quality control parameters:
  - Limit of detection and quantification
  - Sensitivity and selectivity
  - Precision and accuracy
  - Linearity and maximum range
  - Recovery rates
  - Stability



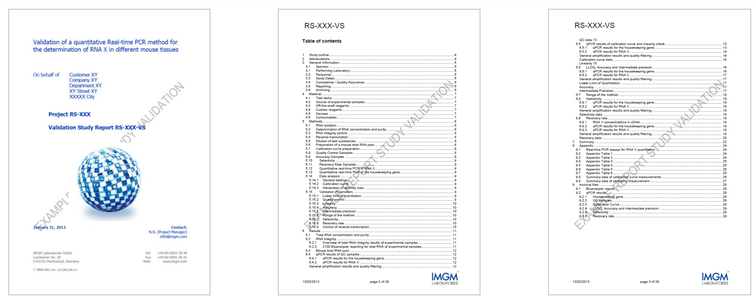

## Main Study

- Absolute quantification of ATMPs by qPCR in triplicates
- Quality controlled and validated qPCR conditions
- Determination of e.g. nucleic acid amount or copies per mg organ
- Assay usable for later phase clinical studies




## GLP-compliant Documentation

- GLP-compliant documentation in submission-ready format
- Comprehensive, high quality study plans and reports
- QA-reviewed
- Consulting on GCP-compliant validation for clinical trials




## IMGM - YOUR flexible and reliable partner for biodistribution, biomarker discovery, pharmacogenetics and metagenomics analyses

- Experts in qPCR biodistribution studies
- Longstanding experience in biomarker discovery
- Experts in metagenomics NGS sequencing
- Pharmacogenetic expertise
- In-depth project consulting
- Latest methods and technologies
- Long track record for customer satisfaction and project success
- Professional quality management system (GLP, DAkkS, DIN EN ISO/IEC 17025)
- Working according to GxP guidelines
- Professional business relationship (e.g. NDAs, FSAs, TATs)

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