REQUEST FOR INFORMATION

ADDING VALUE TO DRUG DEVELOPMENT

aparito

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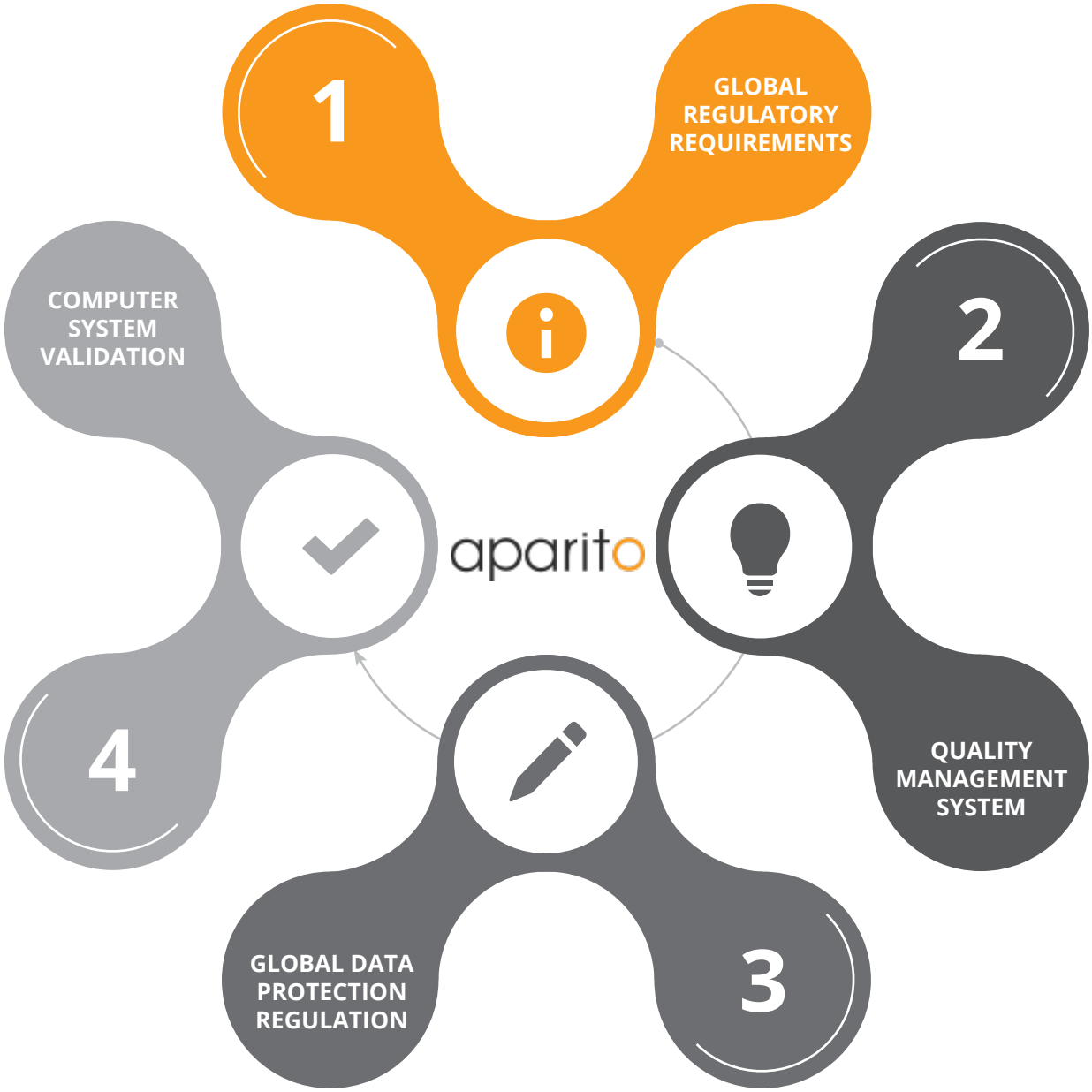
QUALITY ASSURANCE AND SOPS

One of the fundamental value propositions of the project being delivered by Aparito is our expertise in delivering IT solutions to Pharma, Life Science and Research Institutes under regulated conditions. Collectively, the Aparito team have several decades' worth of expertise in several of the key areas that are needed for any project.

Many of our leadership team have extensive experience in regulatory and technical requirements at operational, industry, technical and strategic levels necessary for successful global paediatric and rare disease developments. Such as engaging with patient communities, developing policies and harmonisation at global level, using and developing extrapolation strategies.



QUALITY MANAGEMENT SYSTEM (QMS)

By virtue of the Aparito core technology products being developed in line with the IEC 62304 standard for Software Development Lifecycle (SDLC) and to attain CE marked status for these products under the EU Medical Device Directive, the company already complies with the ISO 13485 and ISO 27001 standards and is in the process of obtaining certification. This means that a comprehensive quality management framework exists that governs the build, release and operation of software. As a result, Aparito will already have most, if not all, of the documentation capabilities this project requires for both EMA and FDA compliance – a feature that might be important if captured data supports research projects.

VALIDATION AND QUALIFICATION OF COMPUTERISED SYSTEMS USED IN CLINICAL TRIALS

The integrity, reliability and robustness of data generated in clinical trials, e.g. data submitted to support marketing authorisation applications (MAAs), are essential to regulators. ICH E6(R2) requires that sponsors operating computerised trial data handling or computerised data systems, amongst others, shall validate these systems, maintain an audit trail for initial entry of data and any subsequent changes, maintain a security system to protect against unauthorized access and maintain a list of the individuals authorized to create, access, modify or delete data. Aparito has a GxP compliant process of establishing and documenting the validation of processes and qualification of the specified requirements for ATOM 5 so that it can be consistently fulfilled from design until decommissioning of the system.

GLOBAL DATA PROTECTION REGULATION (GDPR)

Aparito is registered in the UK with the Information Commissioners Office (ICO) as both a data controller and data processor as we have carried out these roles for clients using our technology to monitor patients in clinical studies. Further, our compliance with ISO 13485 and ISO 27001 means that we have a number of procedures and policies in place as required to meet GDPR legislation from May 2018 that address the following key compliance requirements for healthcare data capture:

1. The ability to maintain comprehensive electronic records when collecting patient data
2. Being able to take explicit consent from patients regarding the capture of their details
3. Being able to take explicit consent from patients for cross-border transfer of their data
4. Being “Disclosure Ready” should a patient submit a Subject Access Request (SAR)

COMPUTER SYSTEM VALIDATION (CSV)

As it is common for customers using our core products to require additional software engineering work to be conducted for their projects, whether that be system integration or simple data management activities, Aparito is able to handle such work in a compliant way. As the company follows a IEC 62304 compliant Software Development Lifecycle (SDLC), we are able to produce documentation as required to demonstrate computer system validation as a standard offering.

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