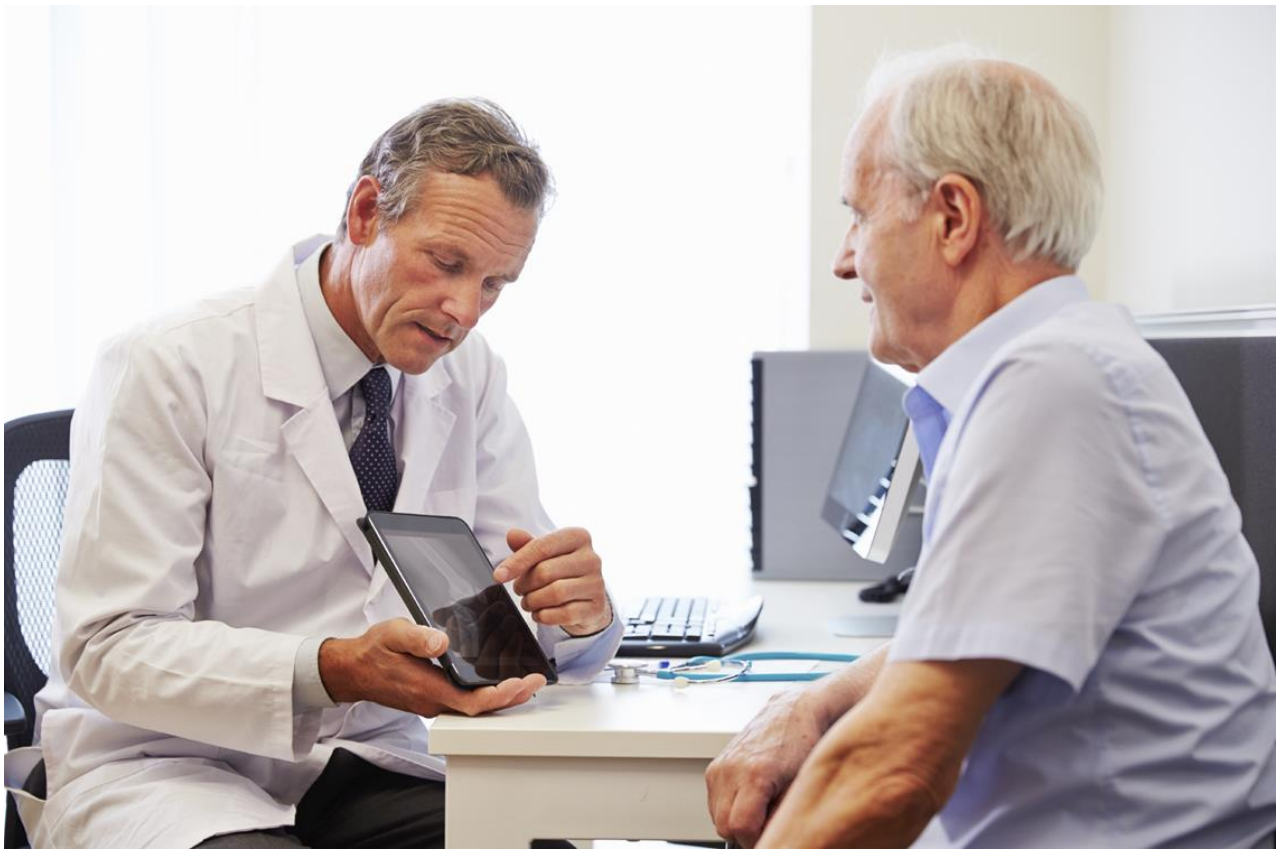
For Immediate Release – May 18th, 2017

Exom Group launched Genius ENGAGE™, the first electronic Informed Consent fully combined with the eTMF

Milano (Italy) – Exom Group, the Human Digital CRO, has launched Genius ENGAGE™, the industry's first ever electronic Informed Consent solution whose digital workflow is fully combined with the eTMF, and integrated with the eCRF, admitting data entry only after the patient has digitally signed the consent form.



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Genius ENGAGE™ allows for a multi-media Informed Consent process on a flexible computer tablet based platform, which is compliant with all legal and regulatory requirements.

The digital backbone of the electronic Informed Consent , is Genius SUITE®, the first multitenant cloud and mobile application that unifies information, documentation, data and processes globally for a single sign-on access and source of truth across any clinical trial.

Genius SUITE®, is the first and only suite of clinical applications that combines in one study portal the following functionalities, to accelerate trial execution and gain real-time visibility into any trial related operations :

- Electronic Informed Consent (ENGAGE)
- Randomization to treatment (IWRS)
- Drug Supply Management (DSM)
- Patient's Recruitment (eENROLL)
- Source Data (eSOURCE)
- Project Management (CTMS)
- Trial Master File & Site File (eTMF/eISF)
- Mobile Data Collection (upCRF)
- Risk-Based Monitoring (RIBAM)
- Real-time Study Metrics (INSIGHT)
- Patient's Visits Calendar (AGENDA)
- Patient's Reported Outcome & Diary (ePRO)
- Safety Report & Management (eSAE)
- Electronic Central Event Assessment (eCEC)
- Certified Trainings (eDOCEBO)
- Quality Management (eQUAM)

"This new process of obtaining the patient's consent to participate to a clinical trial has clear advantages over the conventional way. Now we have a multi media-based informed consent process with real-time tracking options, which provide more consistent and better understanding to study subjects, "

-said Luigi Visani MD, President & CEO of Exom Group -

"Not only can we now document the information provided to subjects, but also their resultant understanding. There is one standardized process with a pre-defined standard across sites, which allows for real-time remote monitoring and audit access. This minimizes legal exposure, reduces potential regulatory findings. Ultimately it will enable remote study models, such as patient-centric or site-less clinical trials and potentially set new quality standards ".

Additional Information

For more on Exom Group : info@exomgroup.com

About Exom Group srl

Exom Group is "The Human Digital CRO" , that provides cloud technological solutions & value-added services for clinical development of drugs & medical devices. We combine the strong medical, regulatory and operational expertise of our staff , with the most disruptive digital cloud technological solutions to reduce costs and increase quality and performance of Clinical Trials. Exom Group is headquartered in Milano (Italy) and operates in all Europe and USA.

For more information visit www.exomgroup.com