ETHICAL

*"...Trial sponsors should have enough of meaningless software complexity, huge budgets and absurd timelines"* MIMMO GARIBBO - DIRECTOR OF ETHICAL GMBH

# eClinical Cloud Solutions

## COMPLIANT | EFFECTIVE | EASY & FAST

## a Team coming from far away

Ethical GmbH, owned and controlled by GM servizi, is a new venture of a TEAM that has been working in eClinical for longtime.

***Since 1997 our software's solutions supported about 300 international trials with more than 10,000 investigators' sites and hundreds of thousands patients.***

Our story as eClinical developers starts in 1997. As GM Servizi, a small software company based in North West Italy, we were hired to design a web application to collect ADVERSE EVENTS. At that time, the TEAM did not have a clue of what an AE was. Yet our enthusiasm allowed us to learn rapidly how SAFETY and QUALITY ASSURANCE work in Clinical Trials.

In 2001 we started to work for a biotech located in Basel area, namely Actelion. Despite the young age, the startup had a brilliant future waiting for it.

Working with Clinical Development departments ***we delivered so many applications including study tracking, data collection, queries management, coding, reconciliation, adjudication, protocol violations, laboratories, data review, narratives, supply management, documents sharing as many more***.

In fact Throughout the last 12 years we have never stopped working side by side with Actelion and other important customers that helped us completing our experience. Our staff travelled around the world to train investigators and support clinical studies' data management. This allowed our small team to learn a great deal from many bright-minded people.

## eClinical before the Cloud rushed

In 2004, well ahead of Cloud market outbreak, we delivered our first eClinical software as a Cloud service.

Hosted by our data centre and technically managed by our Staff, it was used by customers via standard browser connection. This solution immediately ***simplified the work of customers, who did not have to worry about technical issues, but could focus better on their tasks.***

In 2008 we achieved the ISO 27001 certification assuring that our customers' data are managed with the highest international quality standards.

## The Ethical mission in Basel

Looking for skilled professionals and innovation, we now decided to move to Basel in order to take part in one of the most dynamic Lifescience district in Europe.

As Ethical we want to go further, building over our past experiences. On the one hand, we know that Sponsors' Staff really need faster and simpler software adoption processes. We provide them a mix of "out of the box" effective features and a complete technical infrastructure management. On the other hand, software is only the foundation of our service: quality, empathy, flexibility, customization and openness to integration are our complementary strategic keys.

The name Ethical was chosen precisely for the importance we gave to sensitive data services and to working relationship.

***In a nutshell: we give customers a real experienced ethical team to take care of their issues, not jumbo software systems or nameless support teams.***

# Ethical® Cloud Portals

*no one wants to "start from scratch", every one wants "custom services"*

## eAdjudication® Cloud Portal

Cloud software as service to support Study Leaders, Committee Members, Q.A. Staff across the Clinical Endpoints assessment made by External independent experts. It provides tools/services to allow every assignment completion in a timely, effective and quality controlled way.

### MANAGEMENT OF EVENTS' DATA/DOCS

> creation of the Event information package by single or multi file upload (Word, Pdf, Excel, Images, XML, etc);
> event key data/Document direct import/integration (from SAE, EDC, CTMS, SAS and other external D.M. systems);
> visualization / comparison of data and documents included in the package;
> event documentation update and versioning;
> event package status tracking.

### MANAGEMENT OF THE INDEPENDENT COMMITTEE MEMBERS

> user profiles and roles management;
> dynamic assignment of clinical events to Members;
> users communication and "pending task" notification.

### ENDPOINT ASSESSMENTS

> enforcement of workflows specifically designed to map the Adjudication Charter;
> assessment acquisition through EDC like online assessment forms (single or multi-page);
> "more data required" requests handling / "consensus meeting required" management;
> adjudication process tracking with Audit Trail.

### REPORTING & DATA EXPORT

> smart real time reporting tracking the adjudication operations;
> multi format data export;
> adjudication results direct export/integration (to other Data Management systems).

## E-CRF® eClinical Cloud Portal

Cloud software as service with a complete set of eClinical tools designed to support Clinical Data Capture and Management in a GxP environment.

### *PATIENT DATA COLLECTION*

flexibility and efficiency by a choice of 3 different data collection procedures (EDC) integrated in the same environment.

### *TRIAL INFORMATION MANAGEMENT*

effective and centralized trial project tracking and information management.

### *SCREENING & RANDOMIZATION (IWRS)*

Patients' enrolment and central randomization with inclusion/exclusion criteria validation.

### *DATA CLEANING & DATA CLARIFICATION FORMS*

Manage data cleaning procedures, Queries and DCF keeping integrity, quality and compliance

### *TRIAL INFORMATION PUBLISHING*

Clinical Trials and company information publishing and submission to the Registries of Authorities.

## eClinical software services

included in our standard Software Services:

> unlimited Users Licenses for software;
> system setup with fast express configuration;
> system configuration to map protocols / customer requirements;
> ISO 27001 cloud hosting for system and database;
> data centre, servers and security management;
> users support through integrated HelpDesk system;
> users training and certification;
> validation package & documentation;
> stage clone environment for testing and training;
> easy customization & integration through Professional services.

# Main Staff and Customers

## Ethical main Staff

MIMMO GARIBBO - since 1997 - DIRECTOR

Edu: Business Administration - Cares about Company management and business development.

BEAT WIDLER - since 2014 - HEAD OF QUALITY ASSURANCE

*Managing Partner and co-founder of Widler & Schiemann AG* - For 15 years the Global Head of Roche Clinical Quality and 5 years the Head of Roche Clinical Development UK. Representative for more than 15 years on IFPMA, EFPIA, Interpharma working groups and delegations to Health Authorities.

MAURO FAVERO - since 2005 - QUALITY ASSURANCE

Edu: Engineering - Follows projects from requirements and documents quality compliance. Mauro is a nice person and our customers love dealing with him.

SIMONE SURIANO - since 2003 - SOFTWARE ENGINEERING, R&D

Edu: Engineering - Leads developers and R/D. Simone has a rough temper but he really knows how to make and manage robust software.

CHIARA RAGNINI - since 2009 - SOFTWARE DEVELOPMENT & DESIGN

Edu: Information Technology - Designs systems' mobile interfaces. Chiara is creative and passionate as in all things she cares about.

CARLO ROCCA - since 2007 - CIO & SECURITY MANAGER

Edu: Information Technology - Supports us and our services machinery. Carlo has some dashboards that check 24/7 the systems and speak directly with him.
Security Cop.
Leisure: gourmet, children breeder.

## some of our beloved Customers

### Actelion Pharmaceuticals Ltd

Actelion Pharmaceuticals Ltd is a biopharmaceutical company headquartered in Allschwil/Basel - Switzerland. They are focusing on the discovery, development and commercialization of innovative treatments to serve high unmet medical needs.

### Uppsala Clinical Research Center (UCR)

UCR is an Academic Research Organization which mission is to serve those who work with clinical research, clinical trials, and quality development. Endpoint Adjudication Services are one of the main activity fields.

### Fin-Ceramica Faenza Spa

Finceramica, a company of Tampieri Financial Group based in Faenza - Italy, is specialized in technological development of bio-ceramic materials and custom-made solutions for neurosurgery, cranioplastic and spinal surgery.

### Giuliani Pharma Spa

Giuliani Pharma, a pharmaceutical company based in Milan - Italy, has been working for years on gastroenterology research and development, identifying new approaches in the treatment of inflammatory bowel diseases.

### Stanford Center Clinical Research (SCCR)

has a mission to innovate, support and promote high impact global reaching clinical research to improve human health. The SCCR leverages the physical and intellectual resources of Stanford University and its affiliated teaching hospitals and research centers to achieve this mission.