CUSTOMERS GOALS ARE ALSO ONE OF OUR GOALS
is not only a CRO (Clinical Research Organisation) but also a CSO (Contract Safety Organisation) and Regulatory Affairs Services Company.

Our Mission

We are customer orientated and focusing to the unmet needs of our present and future customers.

We strive for simplicity, selectivity and continuous performance optimization.

High performance, both as individuals and as group. We deliver on ambitious goals, and grow by developing our talents and Personal Leadership.

Thanks to the professional expertise in the pharmaceutical environments reached by its founder and the company personnel, GB Pharma Group is the ideal partner for a wide range of services in:

- Clinical Research
- Observational/Outcome Research Studies
- Pharmacovigilance
- Regulatory Affairs

Supporting customers product development, newly authorized or marketed products related activities.

The added value consists in customer strategic support through all the Clinical and Regulatory activities leading to the placing on the market of the drug.

Strategic business development consulting in the pharmaceutical market (Licensing IN-OUT) is an additional “PLUS”.

GB Pharma Group is able to support its customers both in the business development and growth and in the market strategic decision for the identification of new business areas.

GB Pharma Group is also a Market Authorization Holder and so is a “Pharmaceutical Company” with its own:

- PSMF
- Eudravigilance subscription

For that, it can be “Applicant” for the National and European registration on behalf of the customers.
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### GEOGRAPHICAL REACH

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- Denmark
- Germany
- Greece
- Hungary
- Iceland
- Ireland
- Latvia
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- Lithuania
- Luxembourg
- Malta
- Netherlands
- Norway
- Poland
- Portugal
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- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom
- Switzerland

#### Pharmacovigilance Services
- Albania
- Azerbaijan
- Belarus
- Bosnia
- Canada
- Congo
- Egypt
- Estonia
- Georgia
- Kazakhstan
- Kosovo
- Macedonia
- Montenegro

#### Regulatory Affairs Support
- Algeria
- Argentina
- Australia
- Brazil
- Canada
- Chile
- Colombia
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- Israel
- Peru

#### Clinical Research
- Africa
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- Australia
- Belarus
- Brazil
- Canada
- Chile
- China
- Estonia
- Hong Kong
- India
- Indonesia
- Japan
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- Malaysia
- Mexico
- Middle East
- New Zealand
- Peru
- Philippines
- Russia
- Singapore
- South Korea
- Taiwan
- USA
- Morocco
- Russia
- Saudi Arabia
- Tunisia
- UAE/GULF
- Ukraine
- USA
- Uzbekistan
GB Pharma is a full service partner that can provide support in all stages of clinical development:

- Intervventional studies Phase I and Phase II-IV
- Non Interventional Studies (NIS): Observational Registry (OBS), Epidemiological (EPI), Outcome Research (OR) also for Market Access
- Regulatory Studies (PASS, PAES)
- Medical Device Studies
- Food Supplement
- Ideal partner for No-Profit Studies

We also provide insourcing services, concerning the following positions:

- Project Manager
- Clinical Trial Coordinator
- Clinical Monitor
- Study Manager

Services

- Study Feasibility and Centers Selection
- Study planning and documents preparation
- Regulatory and Ethic Submissions
- Project Management
- Clinical Monitoring
- Safety Management
- Data Management, eCRF development, validation and management
- Statistical Analysis
- Medical Writing
- QA (including Audit) and Trainings on clinical research activities
- Vendor selection, certification and management
PHASE I \ BIOEQUIVALENCE \ BIOAVABILITY

Thanks to our expertise in clinical pharmacology, and in clinical studies successfully performed, 3B Biotech is able to provide an overall evaluation of projects development.

The deep knowledge of Phase I studies allow us to timely provide comprehensive quotations of studies/projects performed.

- Single ascending dose tolerability & pharmacokinetics (First in man)
- Multiple dose tolerability & pharmacokinetics
- Local tolerability & sensitisation potential
- Photo-toxicity and photo-sensitisation
- Evaluation of gastro-intestinal tolerability of drugs by gastroscopy and by measuring sugars permeability
- QTc prolongation studies
- Drug-interaction studies
- Single / Multiple dose pharmacokinetics
- Bioavailability
- Bioequivalence

Through a qualified vendor, 3B Biotech is able to perform:

- Toxicity and mutagenicity studies
- Research of bacterial endotoxins with qualitative and quantitative methods (LAL)
- Biological assays in general.
**INTERNATIONAL ACTIVITIES**

3B Biotech Research is part of a network of CROs which allow to cover international trials. All Partners, mid size full service CROs, have been audited considering “Evaluational and Qualification” process.

**Local Services**
- Document adaptations
- EC/CA submissions
- Site management
- Monitoring

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**Central services:**
- Document design
- PM/Oversight
- Central Monitoring
- Site payments
- DM, eCRF React
- Safety DB Analysis
- Report
Main Therapeutical areas (including an important experience in rare diseases)

Other therapeutic areas covered
- Immunological Diseases
- Metabolic diseases
- Gastrointestinal Diseases
- Gynecology / Obstetrics
- Nephrology
- Ophthalmology.

Contrast Media
- Urography
- Angiography
- CT scan
- Pan angiography.

Other therapeutic areas covered
- Oncology
- Hematology
- Infectious Diseases
- CNS (Central Nervous System)
- Cardiology-Cardiovascular-Anticoagulant
- Pneumology-Allergology
- Orthopedics
- Endocrinology, Growth Hormone And Reproduction
- Urology
- Dermatology
Focus on NIS \ Non Interventional Studies

GB Pharma has a proven and long experience in Post-marketing and Observational studies (Non Interventional Studies (NIS): Observational Registry (OBS), Epidemiological (EPI), Outcome Research (OR), and Market Access and it is able to provide a full service at all stages:

- Concept design
- Patient enrolment
- eCRF and data management
- Statistical analysis
- Final publication.

“Observational Studies have an important role in the comprehensive development and testing of a drug and, when conducted properly, provide valuable information to complete drug life-cycle. They provide evidence of effectiveness, tolerability and safety in real-life routine clinical practice”
GB Pharma Group is also able to support in the regulatory submission and conduction of:

**PAES** (Post-Authorization Efficacy Studies)

**PASS** (Post-Authorization Safety Studies)

We have experience in the preparation and regulatory submission and in the conduction of:

- ✓ **PIP** (Pediatric Investigational Plans) or PIP waivers: meeting and submission to PDCO
- ✓ **ORPHAN DRUGS**: submission/designation to COMP and following clinical development plan
- ✓ **Preparation of Clinical Development Plan**

The rigorous approach to the trial conduction together with the experience to the global IMP development, helps to focus on the goal of SPEEDING THE TIME TO MARKET.
GB Pharma designs, provides and validates its eCRF. Although technologically advanced, it is simple, user friendly and able to guarantee security and flexibility in the management of Clinical Trials, Observational and Epidemiological Studies.

Specific features for interventional trials:
- Secure transmission of sensitive data: HTTPS SSL3 protocol implementation
- Audit trail
- FDA 21 CFR Part. 11 compliant
- GAMP 5 validation SOPs and documentation

For NIS/Outcome Research studies, eCRF designed according to sponsor’s request

Cloud Imaging
- Cloud storage images management of (e.g. RMN, TC scan, etc..) via validated devices; data are encrypted and anonymized before the upload
- Interaction with GB Pharma eCRF
**GB Pharma** can provide **BioEquivalence** and **BioAvailability** studies through QUALIFIED VENDORS in Italy and abroad, DIRECTLY controlled and supervised.

We can take care of the whole study:

From study concept, protocol preparation and CRF (e-crf) To clinical site management, monitoring (up to PK analysis and final PK), statistical and clinical report.

We ensure the highest quality standards to ensure that all activities are performed according to our SOPs and in compliance with GCP, GVP, GLP and the applicable regulatory requirements.
PRIOR TO STUDY INITIATION

Vendor selection and audit (GMP, GLP)

Quality Check of the study documentation:
- Study Protocol
- IMP Randomization, Labeling and Blinding procedures
- CRF Design, Annotation and Logical Checks
- Patient Information Sheet and Consent Form (PIS/ICF) for study
- PIS/ICF for Treatment of Personal Data
- Master Clinical & Financial Agreement with Clinical Sites
- CTA Form and Other Documents to be submitted to CA and ECs
- Monitoring Plan and Data Management Plan
- Data Validation Plan

DURING THE STUDY

- Internal audit on Sponsor File
- Site Audits (Routine And/Or “For Cause”)

END OF STUDY

- Quality Check of Clinical Database
- Quality Check of Clinical Study Reports
- Quality Check of TMF
**GB Pharma** employs a team of experienced Medical Writers who can give support at all stages of product development:

- Preparation of study protocols
- Study reports
- Posters
- Manuscripts for publication
- Submission of regulatory documents (including e-CTD).

Beyond the high level of know-how for MW projects, **GB Pharma** can count on further support of a network of experts in medical, scientific and technical areas.

**Management and regulatory documents for clinical trials:**

- Protocols for clinical trials
- Reports of clinical trials, with the help of experts in specific therapeutic areas (grouping, statistical analysis, data writing and report generation in English / Italian,)
- Drug Safety Summaries (Summary data on efficacy and safety)
- Final Study Reports
- Investigator’s Brochures (analysis of literature, publications of the last 10 years, medical reviews, with the use of Database (DB) as EMBASE, PubMed)
- Clinical Overview and Clinical Expert Statement Form 2.5 CTD
- Brochures.
GB Pharma has developed an extensive experience in managing medical devices trials within different therapeutic areas:

- ICD in patients with atrial fibrillation
- Drug eluting stent in the treatment of coronary artery lesions
- Safety and efficacy of stent in acute myocardial failure in patients with angioplastic
- Natural knee in patients with arthritis, osteo-arthritis
- Implantable cardioverter defibrillator (ICD) in patient at sudden death risk
- Cardiac resynchronization therapy-defibrillator (CRT-D)
- Phrenic nerve stimulator.
- Closed Loop Stimulation (CLS) in tilt-induced cardio-inhibitory reflex syncope.
- Study verified by ILR in patients with unexplained syncope
All the Pre-Marketing Pharmacovigilance activities are coordinated and supervisioned by the Clinical Operations Manager and by Drug Safety Coordinators.

Clinical Trial Adverse Events / Adverse Device Effects

Reporting according to GB Pharma specific SOPs based on Directive 2001/20/EC (interventional trials), or Directive 2001/83/CE (NIS) and following updates, or based on ISO14155 (medical devices).

Adverse events and safety reports management:

- Receipt and registration of AEs / SAEs
- Evaluation of “Seriousness”, “Expectedness” and “Relatedness” by Drug Safety Officers and Medical Advisor
- Follow up requests
- Central Triage in Safety DB
- Data Entry
- MedDRA coding
- Quality Control
- “Narrative” preparation
- Medical review evaluation
- Final Assessment

- Safety and Clinical DB “reconciliation”
- Preparation of DSUR

SUSAR Management

- Generation of XML file for Eudravigilance
- Management of EV messages
- Preparation and notification to CA / EC
- Preparation and notification to Investigators
- Notification to Sponsor
- Notification tracking
GB Pharma provides a full range of audit services for the client. The range of services provided by our Group covers all aspects of GCP and GVP and are customized to meet individual customer needs:

- Quality System Management
- Vendor selection auditing for qualification (GMP, GLP, GCP, GVP)
- Clinical Research and Pharmacovigilance (GCP, GVP) Internal and external audits
- Quality control and routinary support
As defined in the European directive 2010/84/EU the MAHs is required to maintain always available the Pharmacovigilance System in order to harmonize and strength the conduct of pharmacovigilance activities in the EU.

Legal requirements are defined in Regulation 520/2012 and further supported by the guidance in Module II of the “Good Vigilance Practice“.
A Qualified Person Responsible for Pharmacovigilance (QPPV) acting on “Sponsor behalf” and “QPPV Deputy” with Backup services 24 hours / 7 day

The QPPV as “owner” of Pharmacovigilance System Master File (PSMF) and whole management of role in strict collaboration with MAH

PSMF-Online Platform available for PSMF “Lifecycle”

PHV Local CONTACT IN every 28 EU COUNTRIES on behalf of the client is offered if needed also a position of PHV Local CONTACT in every EXTRA UE COUNTRIES where client is distributing medical product or where is MAH

Renting / Hosting it’s own Validated Safety Database (in compliance with E2B R3 ich HL7 standard)

Database management - ICSR, ADR, SAE, SAR, SUSAR

Pharmacovigilance Training of company personnel

Risk Management Plan preparation

Signal detection on routinely basis

Periodic Safety Update Report (PSUR) preparation PSUSA / PBRER

Managing Spontaneous ADR (Local, Library Search, Extra EU)

Literature screening (local/international)

Eudravigilance’s management on client’s behalf

Pharmacovigilance Audit

Safety DB Case entry >> Eudravigilance - EMA Database via XML/Postfunction or Gateway

RFN (Rete di Farmacovigilanza Nazionale) NPN (National Pharmacovigilance Network) cases download on the customer’s behalf

Company Core Safety Information preparation (CCSI)

PHV QMS applied through:

- PHV Quality Manual
- GB Pharma Standard Operating Procedures (SOPs), also for preparation/implementation of Client Regulatory SOPs as part of MAH’s PSMF
- PHV Training
- PHV Quality Compliance
- PHV Audits
Medicinal Products Registration in Italy and EU Countries

Regulatory, strategic and operational support through all steps of the registration both with National Procedure and with European Procedures.
Pre-Authorisation Activities

- Legal framework examination for a rational product development;
- Strategic advice on the PK/Phase I/Bioequivalence studies and subsequent conduction of clinical studies;
- Partnership discovery support for chemical and pharmaceutical development, analytical, stability tests, bioequivalence study, etc.;
- Legal basis identification for the registration;
- Gap analysis of preexisting registration dossier (module 3-4-5);
- 648/1996 Application, preparation, review and evaluation;
- Reference Member State identification for European Procedures;
- Pre-submission meeting with competent authorities;
- Scientific Advice submission of the supporting documentation;
- Registration Dossier preparation, editing or review(modules 1-5 in CTD or e-CTD format);
- Preparation of specific documentation in accordance to national requirements;

Post-Authorization Activities

GB Pharma offers support for all the regulatory activities for the MA maintaining through the entire life-cycle of the medicinal product, both with back office mode and in house:

- Preparation, review and submission of administrative, quality and safety variations;
- Line-extension applications;
- Renewal Applications - preparation, review and submission;
- Preparation and review of Quality, Non-clinical and Clinical Overview for Variations and Renewals;
- Gap-analysis for the alignment of obsolete dossier according to current requirements;
- Updating of the texts according to Core Company Data Sheet;
- Conversion of dossier in NtA98 or prior format into CTD or e-CTD.
- Supply of pharmaceutical bollini services;
- GB Pharma provides insertion and updating of the product information in the Farmastampati database;
Start up advisory support to international Companies.

**GB Pharma** offers integrated services for Regulatory, Market Access and Reimbursement; Pharmacovigilance and Medical-Scientific Services.

This service consists of but it is not limited to:

- Set up strategies (legal representation, local representation, attorney, dealership agreement, distribution agreement, etc.)
- Representation of international Companies (assistance in steps required for the recognition of the company from HA; SIS code; AUA and users for the utilities AIFA Front End);
- Support for regulatory planning and logistics including the supply of pharmaceutical bollini though on line procedure).

Pricing strategies analysis and definition according to the current legislation: Price and Reimbursement Dossier preparation, and assistance in negotiating with Health Authorities.

Submission of new products for inclusion in the reimbursable products list, through the critical data process review and the product cost/benefit ratio analysis.

Insertion and maintenance of the products in PTOR;

Support for HTA analysis, budget-impact studies and pharmacoeconomic studies.
Due diligence

Due diligence - legal framework examination for a rational product development and for pre-existing products.

Product documentation examination and issues reporting, in order to avoid additional costs due to documentation request or possible future regulatory issues.

Readability user test

Support for the preparation of the section 1.3.4 of the registration dossier for new marketing authorization (national or European).

GB Pharma realizes Readability User Test at all stages: protocol, interview questionnaire and document preparation, candidates recruitment, interviewer instruction, mock Readability User Test generation, statistical analysis of the interview results and final report generation in Italian or English.

Regulatory support in Extra-EU Countries

- Support for the medicinal products registration and maintenance in Extra-EU Countries (e.g. Middle East, North-Central and South America, Asia, Africa, etc.), in accordance with local legislations and requirements.

- Registration dossier development and support during all registration phases, also with cooperation with local agencies.
GB Pharma assumes the role of proxy with AIFA and other competent authorities (Ministry of Health, ISS, Embassies, etc.) on behalf of the clients.

**GB Pharma delegated services:**

- Managing contacts with competent authorities regarding medicinal products and related procedures;
- Activating and managing contacts with the Ministry of Labour, Health and Social Policies regarding medical devices, cosmetics, food supplements and advertising;
- Collecting and transmitting permits, requests and decrees pertaining to the clients;
- Carrying out all acts of ordinary administration necessary and appropriate for the exercise of the powers hereby assigned;
- Preparing all correspondence and documents related to the role and delegated activities;
- Follow up with competent authorities pending procedures, liaising with the competent officers for the resolution and prevention of critical issues.

**Medical Devices**

- Technical documentation verification for conformity and requirements;
- Medical devices notification in the Ministry of Health database;
- In vitro diagnostic devices notification to the Ministry of Health;
- Technical dossier preparation;
- Consultancy for obtaining the CE marking;
- Obtaining Certificates of Free Sale;
- Authorization request, including advertising material revision.

**Special foods and food supplements**

- Labeling requirements, notification, claims evaluation and advertising.
- Labeling check and information defining to be included on the label in compliance with the current legislation.
- Notification to the Ministry of Health.
BUSINESS & MARKETING STRATEGIES

GB Pharma is able to identify and select the right partner or product in accordance with the Clients’ needs, and in collaboration with their relevant business units.

LICENSING - IN

The licensing-In activities allow the client to enhance its current portfolio and future business with the most suitable products for its needs.

GB Pharma Identify:
- market opportunities in different therapeutic areas
- the most suitable partner.

Evaluate:
- the global market (both drugs on the market and on development).
- the potential of the products.
- all the technical aspects of the Dossier (Due Diligence).

Support:
- the client in negotiating, finalizing and renewing contracts.

LICENSING - OUT

The licensing-Out activities allow the client to find the right partner for its products in different market areas.

GB Pharma Identify:
- the most appropriate partner.

Evaluate:
- the product potential and the partnership in each territory.

Support:
- the client in negotiating, finalizing and renewing contracts.
Mission and Values

“Our goal is to help and support pharmaceutical companies in their business decisions by providing experienced and qualified approach as a guarantee of success.”

The presence within the Group of a business unit tailored to meet the customers’ needs, allows to establish with them a strong partnership based on shared knowledge.

Due Diligence & Audit activities for:

- Regulatory Affairs (Technical Dossier Status, updating, etc.)
- Manufacturing situation according to GMP
- Medical and Pharmacovigilance
- Clinical & Statistical Reports
- Clinical Studies (pipeline, etc.).

Portfolio Evaluation

Most Pharmaceutical and Biotechnology industries require a team of external support in order to make the best decisions about product Portfolio.

GB Pharma has the knowledge and experience to assist companies in making the right decision for business development strategy

- Competitive Market Analysis
- Market Research
- Supporting Decision.

GB Pharma works with new companies that want to enter the market and already well-established companies that want to increase their portfolio with new products and technologies.
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