



# *FOCUS Ethnicity Studies & Bridging Concepts*



Global reach: established & emerging markets



## *for established & emerging pharma markets*

Globalisation and presence in emerging markets worldwide is key to future growth of the bio-pharmaceutical industry.

Consequently drug regulations (i.e. US-FDA) require sponsors of NDAs to present a summary of safety and effectiveness data by demographic subgroups (age, gender, race), as well as an analysis of whether modifications of dose or dosage intervals are needed for specific patient populations. Differences in patient response to drug products have already been observed in racially and ethnically distinct population subgroups. The sensitivity of the medicine to ethnic factors determines the amount of work to design and complete the clinical data package.

The Gaiyo Tokyo Decree of 2006 made bioequivalence data from Japanese subjects mandatory for package inserts, also for foreign generic products.

### ***FOCUS Phase I / Bridging Studies***

- Explore and explain genetic variability and differences in PK / bioavailability / dietary effects or drug response
- Start global development or complement your core programme covering major populations of established and new emerging markets

### ***FOCUS Phase II / III International Multiethnicity Trials***

- Global Clinical Trials including different ethnic populations require PK-information prior to or in parallel with a global exploratory dose-finding study.
- Design global patient programme and gain access to appropriate patient pools
- Incorporate knowledge regarding ethnic subpopulations in the process of dose selection and safety / risk assessment

### ***FOCUS Bridging Concepts: Extending products to foreign markets***

- Extend your market reach with a tailor-made ethnicity bridging project
- Gain foreign market approval at reduced cost for registered as well as for new products

## FOCUS Bridging Concepts

*Extending products to foreign markets*

*Our track record:*



### *Bridging Projects to optimize use and acceptance of existing data for foreign registrations*

FOCUS has developed over 14 Bridging Concepts in the last 3 years. Our experience includes bridging from Western markets (EU and USA) to Japan, EU to Brazil, Russia to EU, Indonesia and India to EU and vice versa. By understanding the differences in local cultural, medical, legal and industry practice we can anticipate many potential short-comings before the data will be reported and presented to the respective authorities for the first time.

### *Definition of an optimal and acceptable regulatory path for the new individual market*

Except for plain generics, there is no such thing as a standard regulatory path for a given compound. The specificities of a given product require a concise description of the benefits and risks of the new product as compared to existing therapies.

Many foreign product dossiers contain too many studies. Existing guidelines provide ample space and guidance to define a stringent yet convincing plan.

In the last 3 years FOCUS has at the request of our sponsors discussed and successfully completed several development plans with the EMEA.

### *Communication between local project management and authorities on similar cultural and academic level*

An efficient and intimate communication with regulatory authorities is key for a successful submission - before and during the development of the product.

Bridging projects comprise team members from both cultures understanding the work performed and planned, and how to improve existing study designs and reports, as well as knowing about differences in medical practice and local markets.

FOCUS has industry experts from Europe, India, Indonesia, Japan, Russia, and USA who have successfully driven international and global development projects.

### *Involvement of key opinion leaders in advisory boards and data safety committees for novel products*

FOCUS can build on a strong network of key opinion leaders from all major therapeutic areas and different regions.



## **FOCUS Ethnicity Studies**

Emerging markets and the global drug development approach have triggered the relevance of population subgroup studies and ethnicity data analysis.

Ethnic factors can be defined as **intrinsic characteristics** (e.g. genetics, metabolism, elimination, skin structure and physiology) of the patient and **extrinsic characteristics** associated with the environment and culture in which the subjects reside.

One of the biggest differences among extrinsic factors and very reluctant to harmonization is medical practice. It is widely recognized that medical practice as well as evaluation of endpoints can be more variable than we think.

Thus, guidelines recommend using a standardized approach for collecting and reporting race and ethnicity information in clinical trials. FOCUS is performing such studies inhouse.

A Bridging Study is defined as a study performed in a new region or population to provide clinical data on pharmacodynamics, efficacy, safety, dosage and dose regimen that will allow extrapolation of the foreign data to the new region.

When no bridging study in patients is needed, a PK-study in the new region or population may be considered as a bridging study. [Source: ICH E5 (R1) Guideline (1998)]



### **Bridging Expertise**

In the last 5 years FOCUS has completed over 25 bridging studies.

FOCUS has built up healthy volunteer panels of different origin: White (Caucasian Europeans), Asian (Japanese, Chinese) and Black (African), following the classification of race according to US-FDA Guidance Document Sept. 2005/OMB-Directive 15.

FOCUS staff and study teams include native speakers for volunteer recruitment and effective study related communication, our experienced medical staff ensures top quality conduct and standardized interpretation of phase I inhouse studies.

Ethnicity studies in healthy volunteers are performed in the FOCUS Clinic Duesseldorf / Neuss while patient studies are shared between different FOCUS Clinical Research Units located in top university hospitals.

#### **FOCUS track record:**

The following study designs have been used:

- PK/bioavailability
- PK interaction
- Repeat dose tolerance study
- Effect of diet on PK
- Female hormone PD-study
- Clinical efficacy study

## FOCUS Bridging Studies

### **know-how**

*Proven track record in clinical pharmacology and drug development*

### **experience**

*Science- & project-based expertise of multinational staff*

### **data acceptance**

*West-East and East-West bridging data accepted by regulatory authorities*

**FOCUS Clinical Drug Development GmbH** ([www.focus-cdd.de](http://www.focus-cdd.de)) is an independent full service drug development house. The unique combination of drug development and clinical pharmacology know-how, plus an in-house infrastructure to manage different population aspects of a programme ensures fast results at high quality standard. We provide product consultancy, regulatory strategy and development planning for New Chemical/Biological Entities, herbal products, biosimilars, generics plus and drug combinations (FDC).

FOCUS Headquarter is located in Neuss/Duesseldorf, Germany with affiliates in Heidelberg, Basel, Belgrade, Moscow, Dubai and Jakarta. Since its inception in 1992 FOCUS has successfully grown to become an established provider of comprehensive NCE/NBE development services to global pharmaceutical and biotech companies.

### *We FOCUS on:*

- **Regulatory Path Finding and Development Planning**
- **Integrated Product Development Management with internationally accepted data package**
- **Global Phase I and rapid Clinical Proof of Concept Phase II studies**
- **Biomarker & PK-genotyping Laboratory**
- **Ethnicity Bridging Concepts**
- **Clinical Research Programmes covering EUROPE - AFRICA - ASIA**



FOCUS Clinical Drug Development GmbH  
Stresemannallee 6  
41460 Neuss - GERMANY

Phone: +49 [0] 2131 155 - 307  
+49 [0] 2131 155 - 225  
FAX: +49 [0] 2131 155 - 394

Internet: [www.focus-cdd.de](http://www.focus-cdd.de)  
E-Mail: [businessdevelopment@FOCUS-CDD.de](mailto:businessdevelopment@FOCUS-CDD.de)  
(for all locations)