SYNCHRON
Good Science. Good People.

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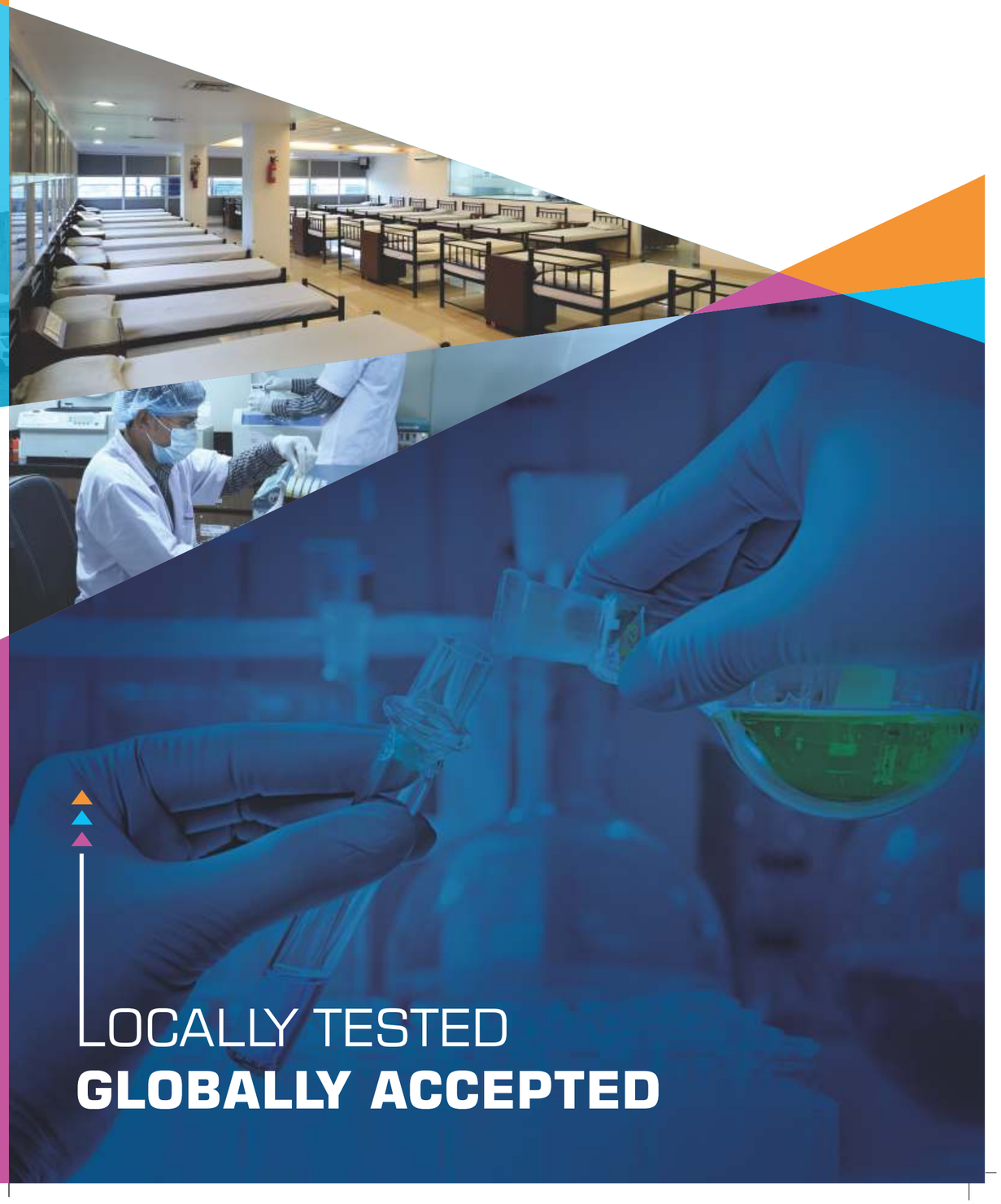

LOCALLY TESTED
GLOBALLY ACCEPTED

Making a difference in everything we do

We believe that true success is not measured by manufacturing innovative products or by assisting in path-breaking clinical developments. True success is reflected in how we make an active contribution in the societies and communities we live in, as well as, the difference we make in people's lives. Synchron has always believed in doing its bit for the society. We want to build a better and sustainable way of life for the weaker sections and assist in our nation's development.

We have undertaken several initiatives under our Corporate Social Responsibility wing and we will continue to do so until we are successful in bringing a measurable difference. We have sponsored various events for charity, especially golfing tournaments as an encouragement for budding golfers of Ahmedabad. All the proceeds from the events go towards ensuring proper education for children in the weaker sections of the society and are focussed on providing them with opportunities that secure a better life. Through these small initiatives Synchron hopes to create a difference in rural communities and thereby, assist in their overall development.

Mr. Sunil Kumar
Golf Pro ,
Playing for Synchron

Our Global Partners & New Businesses

With a view to extending our global footprint in the world of clinical development, we have established ourselves in the Southeast Asian country of Thailand and have associated ourselves with a premiere clinical research organization (CRO) in Bangkok, namely Bio-Innova which was established in 2006.

With this partnership, we have brought an international network of cutting-edge research technologies and international standards in the field of clinical research in Thailand and Southeast Asia.

We put excellence **in everything we do**

Presenting to you the world of Synchron—a front-runner in serving globally-renowned pharmaceutical companies and a preferred partner of several pharmaceutical companies in producing new products for combating illness and diseases, Synchron specialises in strategic development, management and analysis of programs that support clinical development.

Our commitment towards excellence reinforces our aim to serve the clinical development industry with our high standards of clinical trial services. Our emphasis lies in meeting the specific requirements of clients operating in clinical registration of new and ground-breaking pharmaceutical products as well as medical devices ranging from Phase I to Phase IV, including Bioequivalence, Bioavailability, Pharmacokinetic/Pharmacodynamics studies, statistical analysis and data management. We strictly adhere to the ICH-GCP rules at all times, in order to best serve our clients.

Based in India, Synchron's dynamic services are available to domestic and international pharmaceutical companies. Since 1998, the company has made momentous progress in its attempt to expand operations within the country and globally. Our partnership with Parexel International gives Synchron an edge over others in offering exceptional globally accepted clinical research facilities.

We believe we offer incomparable and unrivalled expertise across all verticals under clinical research and through this publication we would like to demonstrate our various offerings.

Dr Shivaprakash Rathnam,
M. Pharm., Ph.D.
Founder & Managing Director,
Synchron Research Services Pvt Ltd.

We are India's answer to Clinical Research

Being a globally renowned clinical research organization (CRO) with an exceptional reputation, Synchron has employed its high-technology resources to help clients achieve accurate results in their research and development goals through true scientific spirit. Stringently following the global standards in clinical trial methodology, and adhering to Good Clinical Practise (GCP) and Good Laboratory Practice (GLP), Synchron has today shaped a name for itself amongst other distinguished CROs in the world.

Our Assurance towards Excellence

In order to maintain our integrity in providing clients with accurate and reliable results, Synchron has a dedicated team working under its Quality Management System (QMS), ensuring investigators and researchers are following the standard protocol, complying with regulatory and Good Clinical Practice (GCP). Our dedicated staff monitors the progress of clinical trials performed by the researchers in order to ensure patient protection and validate the veracity of the data collected.

Following the monitoring process, the significant findings are then escalated for review by the Quality Assurance (QA) departments, which are then managed as suspected significant deviations. Following this process, risk assessments and evaluations are undertaken where remedial actions, which may include notifying regulatory authorities and ethics committees of any significant regulatory and/or GCP requirements are then assumed. For Synchron, adhering to the standard protocols is a must in each of its clinical development activities.

Our QMS Team Activities

- SOP Management
- Document management
- Document Change Control
- Change Control (instruments)
- CAPA (planned/unplanned deviations)
- Archival process.

Our Regulatory Compliance Team (GxP) Activities

- Audit Plans
- In process Audits
- Retrospective Audits
- System Audits
- Investigator Site Audits
- GxP Vendor Audits
- Compliance Review (Protocol, ICF, CSR)
- Hosting External Audits and Inspections

We are globally recognized for our proficiency in Data Management

Our expert staff offers validation in research outcomes for pharmacokinetics data modelling and statistical analysis and data management using state-of-the art equipment and tools, which aid them in their procedures.

Data Management
Our offerings include widespread services in data processing, analysis and management. We have also extended our services into providing validation in hardware and software for data modelling. We are equipped with state-of-the-art infrastructure at our facility and our trained professionals have dedicated themselves in delivering PK/PD modelling and biostatistics to many pharmaceutical, biotechnology and generic companies in India and elsewhere.

Data Management Tools

- SAS®
- Oracle 9i®
- MedDRA®
- Kinetica®
- WHO Drug Reference List®
- Oracle 9I®
- Microsoft Products®
- Watson LIMS®
- WinNonlin®

State-of-the-art infrastructure to conduct **effective trials**

With a total of 90 beds at Ahmedabad, including 3 Clinical Pharmacology Units, Synchron works persistently towards providing accurate and excellent results in clinical trials. Our skilled and trained specialists take utmost care while providing treatments to patients during the trials.

With a large database of healthy volunteers, screened by the Volunteer Project Management System, Synchron has a well-equipped clinic, including 3 ICU beds with equipment such as cardiac monitor, defibrillator, etc.

Clinical Trial Management

Our team of highly-proficient and well-trained administrators and CRAs are in constant touch with clinical sites, investigators and clients across the globe, with the aim of maintaining timely and precise dissemination of vital information.

Clinical Trial Phase II-IV

We have consistently delivered speedy, cost-effective and quality results to our sponsor's clinical projects and have efficiently assisted them throughout their drug development stages.

- Sample size determination
- Patient randomisation
- Ethics committee approval
- Preparation of CRF manual
- Data analysis
- Sample analysis
- Statistical analysis
- Feasibility studies
- PK/PD studies
- Report writing
- Quality assurance
- Post marketing and marketing support trials
- Drug device trials

We create feasible solutions with the help of expert consultants

Our experts have assisted in developing and validating methods for various drugs using high-technology and equipment, while adhering to the US-FDA guidelines. Our modern bio-analytical facility, operated by scientific experts, is completely equipped with high-tech resources and technologies that are in compliance with the Good Laboratory Practice (GLP) and ISO/IEC 17025 requirements. Our hardware and software adhere to the 21CFR Part 11 compliance.

Our capabilities help you find desired and reliable results

Phase I Pharmacokinetic studies

Synchron has been leading a wide range of bio-studies on healthy adults, including males, females, post-menopausal women and special populations, for more than a decade. Our range of work includes bio-availability, pharmacokinetic, pharmacodynamics, bioequivalence, food-effect, drug-to-drug interaction and derma-to-pharmacokinetic researches.

Equipment:

- 10 LCMS MS
- 1XGCMS
- 90 beds

Bio-analysis:

Following the achievement of winning the prestigious Indian Drug Manufacturers' Association research award for bio-analysis both in 2003 and 2007, Synchron has established itself as a leading bio-analysis researcher in India. Our analytical management staff has more than 15 years of expertise and we employ innovative ways in method development that helps us achieve accurate and positive results. We have a highly-proficient staff with GCP/GLP knowledge and a team of well qualified as well as experienced scientists and technicians who work tirelessly to achieve accuracy in results.