Regulatory Environment in South East Asia
ASEAN (Association of Southeast Asian Nations), a growing region in South East Asia, comprises of 10 member countries namely Singapore, Thailand, Malaysia, Indonesia, Philippines, Brunei Darussalam, Vietnam, Laos, Myanmar and Cambodia. As in 2010, the region covers an area of 4.46 million Sq.Km, having a population of approximately 600 million people (about 8.8% of world population). The combined nominal GDP had grown to USD 1.8 trillion with significant disparities prevailing across the region. The pharmaceutical market though being relatively small still attracts many Pharmaceutical companies due to its high growth potential. Five founding member countries Singapore, Malaysia, Thailand, Philippines & Indonesia are more progressive terms of Pharmaceutical market size than the rest of ASEAN countries. As shown in Table 1.

<table>
<thead>
<tr>
<th>Countries</th>
<th>Singapore</th>
<th>Malaysia</th>
<th>Thailand</th>
<th>Philippines</th>
<th>Indonesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average GDP growth (%) (2011-2015)</td>
<td>4.7</td>
<td>5.5</td>
<td>5.2</td>
<td>4.6</td>
<td>6.6</td>
</tr>
<tr>
<td>Pharma Market (2010)</td>
<td>615 million USD</td>
<td>1.4 billion USD</td>
<td>4.04 billion USD</td>
<td>2.75 billion USD</td>
<td>6.05 billion USD</td>
</tr>
<tr>
<td>Growth rate (CAGR) (2010)</td>
<td>5.5%</td>
<td>7.1%</td>
<td>8.44%</td>
<td>4.99%</td>
<td>11.3%</td>
</tr>
</tbody>
</table>

1.0 The Regulatory Environment In South-East Asia

ASEAN’s main purpose is to accelerate economic growth, social progress and cultural development in the region. For several years Association’s Consultative Committee for Standards & Quality have been working towards harmonization of pharmaceutical regulations and this agreement was eventually achieved in July 2009. The harmonization process created transparent regulatory procedures and standardized regulation requirements and removed need for duplicate studies by meeting various regulation requirements and hence allowing drug companies more time and resources for research and development of new drugs. Since 2010, drug companies are going with one set of regulatory requirements for all ASEAN countries as long as it is compliant with ASEAN Common Technical Dossier (ACTD). This harmonization facilitated prospect of multicentre trials across SEA region making it attractive, more cost effective and more straightforward. In SEA, the IRB and regulatory timelines have improved over the past few years. The regulatory agencies have documented specific guidelines for clinical trial approval along with declared timeline commitments. Moreover, IRBs are better organized in compliance with ICH GCP guidelines and approval procedures and timelines are more predictable currently. Joint IRBs have been set up in some countries that eliminate repetitive reviews for multicenter trials. Also, with more experience in
clinical trials, regulatory agencies and IRB’s have gained more confidence in reviewing early phase studies. In Singapore, there has been an increase in number of Phase 1 trials and some of them first in human studies have been approved. Furthermore, for improving overall start-up timeline, many countries have implemented parallel procedures for regulatory and IRB submissions. In a survey conducted across the region showed that for most clinical trials, IRB and regulatory approvals would take approximately 2-4 months and this time period is acceptable for most of the multinational companies who are conducting international multicenter trials. However, this may not be applicable for Phase 1 trial where shorter timeline is required preferably less than a month from industry perspective, which is a challenging issue and hence efforts are being made for making this goal achievable.\textsuperscript{[3,4]}

Regulatory agencies of SE Asia countries have been listed in Table 2. In recent years they have been differently organized and many changes have taken place. These changes were significantly evident in Singapore. In 2001, The Health Sciences Authority (HSA) was formed on 1 April 2001 as a statutory board of the Singapore Ministry of Health with the integration of five specialized agencies: the Centre for Drug Evaluation (CDE); Institute of Science and Forensic Medicine; National Pharmaceutical Administration; Product Regulation Department; and Singapore Blood Transfusion Service. The two centers that deal with drug registration are the \textit{Centre of Pharmaceutical Administration} (CPA), the licensing body that performs administrative work related to drug registration while the \textit{Centre of Drug Evaluation} (CDE) performs scientific and medical evaluations of new drug applications.

**Table 2: Regulatory Agencies in S.E. Asia**

<table>
<thead>
<tr>
<th>Countries</th>
<th>Regulatory Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>National Agency of Drug &amp; Food Control</td>
</tr>
<tr>
<td>Malaysia</td>
<td>National Pharmaceutical Control Bureau (NPCB)</td>
</tr>
<tr>
<td>Philippines</td>
<td>The Bureau of Food &amp; Drugs (BFAD), DoH</td>
</tr>
<tr>
<td>Thailand</td>
<td>ThaiFDA, Drug Control Div.</td>
</tr>
<tr>
<td>Singapore</td>
<td>Health Sciences Authority (HSA)</td>
</tr>
<tr>
<td></td>
<td>Centre for Pharmaceutical Admin. (CPA)</td>
</tr>
<tr>
<td></td>
<td>Centre for Drug Evaluation (CDE)</td>
</tr>
</tbody>
</table>

**2.0 Drug registration in South East Asia**

With ASEAN Common Technical Document (ACTD) entering Southeast Asian market has been considerably easier. With a harmonized dossier for SEA countries such as Singapore, Malaysia, Thailand, Philippines, Indonesia, and Vietnam, Pharma companies can enter these multiple markets at once. ACTD is very similar to ICH CTD with some notable differences.
2.1 Singapore

In Singapore, under Medicines Act, section 5, a product license is required before medicinal product can be sold or supplied unless otherwise exempted under the law. Each product license is specific to a product having a particular name, particular formulation, in a particular dosage form i.e. physical presentation and strength & with a particular set of approved indications and directions for use. If there is any change in above parameters it may result in need to submit an application to vary the existing product license or possibly obtain a new product license altogether. In applying for a new Product License for a medicinal product in Singapore, there are two types of applications: a new drug application (NDA) and a generic drug application (GDA). The NDA is for new drug or innovator product, whereas GDA is for that drug product that is essentially similar to a currently registered product in Singapore (not applicable to biologics). Application submission for product registration involves 2 parts: by on line PRISM (Pharmaceutical Regulatory and Information System) and ACTD/CTD dossier submission. The application to HSA can be submitted using ACTD/CTD format. The CTD provides a common format in preparation of well structured submission dossier. The CTD uses a modular framework as described in ICH Topic M4 or the ASEAN guidance on the Common Technical Document for Registration of Pharmaceuticals for Human use: Organization of the Dossier. The guidance document must be read in conjunction with recent version of ICH CTD and ASEAN CTD (ACTD) guidance documents. Hence submission to HSA will be in one of two formats either ICH CTD or ACTD format. As shown in table 3 below as per the chosen format documents would be grouped in five modules (ICH CTD) or four parts (ACTD); the main difference between these two formats is numbering and naming of sections.\[5\]

<table>
<thead>
<tr>
<th>Documents</th>
<th>Location in ICH CTD</th>
<th>Location in ACTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative Documents and Product Information</td>
<td>Module 1</td>
<td>Part 1</td>
</tr>
<tr>
<td>Common Technical Document Overview and Summaries</td>
<td>Module 2</td>
<td>Incorporated in Parts 2, 3 and 4</td>
</tr>
<tr>
<td>Quality documents</td>
<td>Module 3</td>
<td>Part 2</td>
</tr>
<tr>
<td>Non-clinical documents</td>
<td>Module 4</td>
<td>Part 3</td>
</tr>
<tr>
<td>Clinical documents</td>
<td>Module 5</td>
<td>Part 4</td>
</tr>
</tbody>
</table>

Table 3: Format of the ICH CTD and ACTD\[5\]
Document Requirements \(^{[5]}\)

Language: - All information and documents that supports an application like certificates and approval letters should be in English and authenticated. Documents that are not originally in English should be translated. The documents that is a foreign document and is original with a proper seal and signature of
recognized government agency does not require notarization. For other types of documents that lacks an original sign have to be notarized by notary public in the country where the document was issued before the document can be authenticated. However, notarizations are not required for documents executed and use in Singapore.

**Administrative Documents**

**Comprehensive Table of Contents**
- Introduction (*brief and precise summary for application made with proper justification for its need is required*)
- Application Form
- Labeling, Package Insert and Patient Information Leaflet
- Approved SmPC/PI/PIL
- Assessment Report from Reference Agencies
- Description of Batch Numbering System
- Proof of Approval
- Business Registration Certificate
- Authorization Letters
- GMP Certification/Proof of GMP Compliance
- Patent declaration
- Declaration on rejection, withdrawal and deferral
- Declaration for NDA verification
- Registration status in other countries
- CTD Overview and Summaries
- Quality Documents
- Body of Data – Drug Substance
- Drug Master File (DMF)
- Plasma Master File (PMF): (required whenever a human plasma-derived product is used either as a drug substance or as an Excipient.)
- Certificates of Suitability (CEP)
- Stability Data of Drug Substance
- Body of Data – Drug Product
- Process Validation
- Control of Excipient
- Control of Drug Product
- Stability Data of Drug Product
- Product Interchangeability and Biowaiver request
- Blank Production Batch Records
- Non-clinical Documents
- Clinical Documents
Regulatory Fees

In Singapore, there is a separate fee structure existing for different types of applications (Application for a license – NDA & GDA), license issued for different years and import license. For complete list of fees is as below in website.


2.2 Thailand

The registration of new drug is governed by ThaiFDA. The drug board has monthly meeting and gives recommendations or opinions for licensing & registration decisions regarding approval, withdraw or suspend the licenses. As per the drugs act persons who wish to sell, produce or import drugs into the country have to obtain license from FDA and only authorized licensees are qualified to apply for product registration. Also, the manufacturing plants for drugs should be GMP compliant. The certificate of product registration is valid for 5 years from issuance date. The drug registration process is carried out in 2 channels that differ in degrees of control and dossier submission.

1. Registration of general medicines
2. Registration of Thai traditional medicines

Submission requirements are different with different types of submission, for example general medicines are further classified as Generics (whose registrations require only dossiers on product manufacturing and quality control along with product information), New medicines (whose registrations require a complete set of product dossiers); New generics (whose registrations require dossiers of bio-equivalence studies in addition to the required dossiers for generics submission). There is a 2 year period of safety monitoring program as per the amended registration procedure for new drugs adopted in August 1989. This implies that new drug have to be firstly approved for use only in hospitals/clinics for two years at least. The safety reports generated then needs to be submitted for consideration whether general marketing of drug should be allowed. In the interim, new generic products have to pass BE studies for assuring comparatively therapeutic outcomes. The BE studies data is submitted to authorities as proof of product bioavailability with product information and quality dossiers. [6]

Table 4: Time required as per review types for new and generic drugs registration [7]

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Process of New Drug Registration</th>
<th>Process of New Generic Drug Registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Review</td>
<td>210 - 280 working days</td>
<td>100 - 130 working days</td>
</tr>
<tr>
<td>Accelerated or Priority Review(Drugs for public health problems / life threatening)</td>
<td>110 working days</td>
<td>70 working days</td>
</tr>
</tbody>
</table>
**Documents required** [7]
For new drug registration as per ASEAN Harmonization, ASEAN Common Technical Dossiers (ACTD) is to be submitted and this document is to be submitted in 4 Parts.
Part 1: Administrative Data and Product Information
Part 2: Quality Document
Part 3: Nonclinical Document
Part 4: Clinical Document

**Regulatory Review**
One stop service center has been established for submission of applications that can be processed and approved within a short time period. The fast track pathway for emergent medicines like neoplastic, HIV, Anti-TB, Antiviral vaccine has been created to reduce time period from 280 working days to 130 working days.

**Fig. 3: Flow chart of drug review process** [7]

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www.makrocare.com/Consulting
2.3 Indonesia [8]

Drug is classified into three groups:

1. New Drugs: further divided into New Chemical Entity (NCE), based on new indication and new route of administration
2. Biological Products
3. Generics (branded)

For drug registration, application needs to be submitted by the applicant to the Head of National Agency. Drug registration consists of 2 stages that is pre-registration and submission of the registration dossier. Head of agency is responsible for confidentiality protection of registration data, which is related to evaluation and analysis of drugs.

Pre-registration is conducted to decide evaluation path and completeness of drug registration documents. Pre-registration application must contain all documents as per the requirement stated and completed with search result of drug trade name. Criteria for evaluation path must comply with all requirements and if necessary should be completed with the details of independent assessment report. Drug name can be generic name or a trade name based on General Guideline of Drug Name. The result of pre-registration would be communicated to the applicant in writing and it is binding.
Submission of registration dossier is conducted by using registration forms (Forms A, Form B1, Form B2, Form B3, Form B4, Form C1, Form C2, Form C3, Form D) and floppy disks, completed with all supporting documents and attaching the receipt of payment of evaluation and registration fee and the result of pre-registration. Registration form or floppy disk is supplied by directorate of Drug and Biological Product Evaluation.

Form A contains information about name and address of the applicant and manufacturing Pharmaceutical industry and general information about drug to be registered.

Form B contains documents that cover the aspects of efficacy, safety and the quality of registered drug and is binding, such as Form B1 (administrative documents), Form B2 (product information that cover the aspects of efficacy, safety and quality), Form B3 (the procedure of Batch numbering system) and Form B4 (price information);

Form C contains documents that must be attached to support the information mentioned in Form B2, that is Form C1 (documents on quality and technology), form C2 (preclinical trial documents) and Form C3 (clinical trial documents);

Form D contains a list of the submitted drug sample and its reference standard.

Upon registration of drug, an applicant is required to pay evaluation fee, this fee is in conformity with the provisions of Government Regulation on the Tariff of a type of non tax state income (Penerimaan Negara Bukan Pajak = PNBP) valid to National Agency of Drug and Food Control.

Supporting documents required by registration consist of:

a. Quality and technology documents to ensure the quality of drug.

b. Pre-clinical trial documents, describing the profile of pharmacodynamic, pharmacokinetic as well as safety level for toxicity, before the human clinical trial, and pre-clinical trial report matrix.

c. Clinical trial document that convincingly proves the efficacy and safety of finished drug in compliance & clinical trial report matrix.

Completion of registration forms and documents should be in Indonesian or English. Labeling of over the counter drug/limited over the counter drug must be in Indonesian. Labeling of drugs for exporting only should at least be in English. In completion of registration and other forms guideline must be followed and must conform to standard requirements.

**Timeline for evaluation of new drugs**

Life-saving and breakthrough drugs = 100 working days

Drugs already marketed in harmonized countries = 150 working days

Other New drugs = 300 working days
Timeline for evaluation of generics (branded) drugs

Drugs for exportation and drugs electronically transmitted = 80 working days
Essential generic drugs for public health program = 100 working days
Others = 150 working days.

Fig 5: Flow of registration and evaluation process : Indonesia [9]

2.4 Malaysia [10]

For registration of new product in the country, an applicant is sub-divided into one of the following:

(i) Application for an innovator product (NCE / Biotech) [containing : a new chemical or a biological entity; new combination of existing chemical/biological entity(s); existing chemical or biological entity(s) in a new dosage form; existing chemical or biological entity(s) for use by a different route of administration;
(ii) Application for a generic product (Controlled Poisons & Non-Controlled Poisons)

(iii) Application for product registration via the abridged procedure (for certain categories of OTC products and also for traditional medicines) eg:- antiseptics/skin disinfectants; lozenges/pastilles

The data required to support application includes administrative data (Part I); product quality data (Part II); product safety data (Part III); and product efficacy data (Part IV). The data required to be submitted would be based on application types: Innovator product – Parts I to IV (except for existing chemical or biological entity(s) in a new dosage form which will require only Parts I & II, along with pharmacokinetic data); Generic product – Parts I & II Abridged procedure – Part I only.

The drug control authority (DCA) accepts only web based on line submissions via [http://www.bpfk.gov.my](http://www.bpfk.gov.my) and applicant for product registration must be registered with Suruhanjaya Syarikat Malaysia (SSM) or Malaysian Registrar of Business (ROB). An applicant (if said company is not product owner) should be authorized in writing by the product owner to be the holder of the product registration certificate and be responsible for all matters pertaining to the registration of the product. An applicant is responsible for supplying up to date information with regards to application and supporting documents and updating DCA for any change in product/application (esp. during the course of evaluation, and after product registration, especially if the information pertains to rejection/withdrawal, additional data on product efficacy and safety or current Good Manufacturing Practice(cGMP) compliance of the manufacturers (and repackers, if applicable) and all information given to DCA must be in a timely manner. The application for registration includes with a non refundable processing fee as applicable.

Registration application for new drug also includes:

i. Letter of authorization from the product owner. (not applicable if the applicant is the product owner)

ii. Site where product is manufactured.

iii. Letter of authorization of contract manufacture and acceptance to and from the manufacturer and also each subcontractor, if applicable (e.g. repacker).

iv. Letter of authorization on product owner’s original letterhead, signed and dated by MD, President or CEO equivalent person who has overall responsibility for the company or organization.

v. Acceptance letter from manufacturer complying with similar requirements as above.

vi. For imported products require either Certificate of Pharmaceutical Product (CPP) from the competent authority in the country of origin OR Certification for Free Sale (CFS) and Good Manufacturing Practice (GMP) from the relevant competent authorities as acceptable by DCA for traditional medicines and dietary supplements (CPP shall be in format of WHO certification scheme. CPP’s issued by EMEA for those products registered through centralized process in EU are acceptable. CPP’s issued by the manufacturer or other authorities are not acceptable. For more than 1 manufacturer involved in manufacturing GMP certification is required.)
A separate application is required for each product i.e. products having same ingredients but made with different specifications (with respect to strength/content of ingredient, dosage form, description, etc) or by different manufacturer.

**Regulatory review**

Application review follows a queue system. There are separate queues for different categories of products: NCE, Biotech, Generics (full procedure), Abridged Procedure Pharmaceuticals (OTC), and traditional Products. If the product is meant for serious or life-threatening disease, a priority review may be granted. An application for registration for new product would be rejected if no required additional data is submitted by applicants within 6 months from the last correspondence date for NCE/biotechnology products (for all other products 90 days is allowed) An e-mail is sent to applicants about decisions of DCA regarding approval/rejected application. Product registration number is assigned if product satisfies all requirements of quality, safety and efficacy and is granted registration approval by the DCA and this is specific for that particular product only and accordingly product registration certificate is issued implying the provisions, conditions, and limitations etc. of the registration.

A written appeal to Minister of Health or the Director of Pharmaceutical Services if decisions of the DCA is not binding by applicant and must be made within fourteen (14) days from the date of the DCA notification.

**2.5 Philippines**

In order to ensure efficiency and harmonization of standards for evaluation of new drugs, The Bureau of Food & Drugs (BFAD) is authorized for adopting measures and methods addressing drug evaluation issues not otherwise addressed by earlier administrative & regulatory constraints. Applicants need to submit registration dossier in accordance with ACTD (Asean Common Technical Document) format for registration of new drug. The contents include administrative data, quality data, Non Clinical and clinical data (fig. 6.). An application for drug registration of pharmaceutical products already in foreign markets are evaluated from the data submitted to Drug Regulatory Agency of the country where it is marketed and other post market data that supplements or serves as an alternative measures for existing regulatory requirements without undermining domestic standards on safety, efficacy and quality of drug products. Informational requirements under new drug application summary include: \[11\]

a. Proposed text of labeling of Pharmaceutical product with appropriate information in summary and technical sections that support the addition of any statement in labeling.

b. Statement that indicates pharmacologic class of drug and scientific justification of drug (clinical indications and therapeutic benefits).

c. Brief description of marketing history that includes countries where drug has been marketed or withdrawn for safety and efficacy reasons and also countries where applications are pending if any.

d. Summary of chemistry, manufacturing and control section of application.
e. Summary of human pharmacodynamic & pharmacokinetic bioavailability.
f. Summary of microbiology (for anti-infective only)
g. Summary of clinical data section of application
h. Concluding discussion stating benefits and risk considerations of drug.
i. Discussions of proposed PMS/monitored release study after approval of drug
j. Information from IB that shall be subjected to BFAD audit and verification.

Organization of registration dossier in accordance with ACTD format

1. ASEAN Glossary
2. Organization of the Dossier
   2.1 Part I. Table of Contents, Administrative Data and Product Information
      Section A: Introduction
      Section B: Overall ASEAN Common Technical Dossier Table of Contents
      Section C: Documents required for registration (for example application forms, Labeling, Product Data Sheet, Prescribing Information)
2.2 Part II Quality Document
      Section A: Table of Contents
      Section B: Overall Quality Summary
      Section C: Body of Data
2.3 Part III Non Clinical Document
      Section A: Table of Contents
      Section B: Non Clinical Overview
      Section C: Non Clinical written & Tabulated Summaries
      1. Table of Contents
      2. Pharmacology
      3. Pharmacokinetics
      4. Toxicology
      Section D: Non Clinical Study Reports
      1. Table of Contents
      2. Pharmacology
      3. Pharmacokinetics
      4. Toxicology
2.4 Part IV Clinical Document
      Section A: Table of Contents
      Section B: Clinical Overview
      Section C: Clinical Summary
      1. Summary of Biopharmaceutics and Associated Analytical Methods
      2. Summary of Clinical Pharmacology Studies
      3. Summary of Clinical Efficacy
      4. Summary of Clinical Safety
3.0 ASEAN Regulatory Harmonization Initiative

Owing to many regulatory barriers and diversity of required documentation that was hindering simultaneous submissions in SE Asia, ASEAN countries started regulatory harmonization initiative in 1999, this initiative was known as ASEAN Consultative Committee for Standards and Quality – Pharmaceutical Product Working Group (ASEAN CCCSQ-PPWG) which was aimed for establishing common technical requirements & developing quality guidelines for product registrations. The ASEAN mandated filing of ASEAN Common Technology Dossier (ACTD) as the only regulatory filing for Pharmaceutical companies for getting approval of drugs in 10 member states of Singapore, Malaysia, Indonesia, Philippines, Thailand, Vietnam, Brunei, Myanmar, Cambodia and Laos, with effect from 2012. The main aim was to create transparent regulatory process, standardization of regulatory requirements and remove any need for duplicate studies for meeting various regulation requirements thus allowing drug companies more time and resources for R & D on new drugs. This would eventually allow more time and resources for drug companies in speeding up R & D process for new drugs. The anticipated benefits that association expects are that member countries would be benefited by lower costs and increase quality and availability of medicines in the region. Also, formulation of rules for import of medicines for ensuring quality of drugs in region and rejection or alert of a product in one country would be applicable for all member nations.

4.0 Clinical Trials in South East Asia

Pharmaceutical companies are making considerable changes to counteract negative impacts resulting from patient expirations and generic competition, rising R & D costs, falling productivity, pricing pressures and hostile regulatory environments for ensuring future success. To counteract this and improve R & D productivity large number of US & European Pharma majors have adopted global drug development and outsourcing strategies that extend their clinical trial activities to emerging markets destinations expecting faster patient recruitment and save cost. This shift in market dynamics towards emerging markets especially Asia would promote placement of trials in Asian region. Globalization of drug development and trend with regulatory changes in SE Asian countries has placed high demand on Asian sites and stimulated growth of clinical trial market in this region. In SEA, Singapore, Hong Kong, and Taiwan are more developed and well equipped with better infrastructure for conduction of trials than other countries. This sturdy growth in trials is reflected by increase in number of clinical trial approvals issued by regulatory agencies since 1995. Large numbers of trials are part of international multicenter studies sponsored by major pharmaceutical giants. Presently Malaysia, Thailand, the Philippines, and, lately, Indonesia & Vietnam have increased their infrastructure facilities for clinical trial. Most countries in SEA region have trials conducted being part of international
multicenter Phase III studies (> 70%), followed by Phase II. In Singapore, the country is well equipped with two Phase I units to have early phase trial conducted supportive of companies pipeline development. Therapeutic areas in focus in SEA region are Oncology, cardiovascular diseases, infectious diseases, metabolic diseases, and diseases of the central nervous system are the major specialties that have attracted the most study protocols. Analysis conducted showed that region showed positive sign and opportunities were remarkably greater than threats and strengths outweighed the weaknesses. The IRB and regulatory timelines have improved over past few years. Also, IRB’s are better organized in complying with ICH GCP standards and IRB approval procedures and timelines are more predictable. Moreover, joint IRB’s have been set up in some countries to eliminate repetitive reviews for multicenter trials. With enough experience in clinical trials regulatory bodies and IRB’s have gained confidence for reviewing early phase studies. For improvement of overall start up timeline many countries have implemented parallel procedures for regulatory and IRB submissions.\footnote{14}

![Fig. 6: IRB & Regulatory Approval timelines \cite{14}](image)

<table>
<thead>
<tr>
<th>Country</th>
<th>Total (Months)</th>
<th>Regulatory (Months)</th>
<th>IRB (Months)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singapore</td>
<td>1 to 2</td>
<td>1 to 2</td>
<td>1 to 2</td>
<td>Parallel Submission; Cluster IRB</td>
</tr>
<tr>
<td>Malaysia</td>
<td>2 to 3</td>
<td>1.5 to 2</td>
<td>1 to 3</td>
<td>Parallel Submission; network IRB</td>
</tr>
<tr>
<td>Philippines</td>
<td>2 to 4</td>
<td>1 to 2</td>
<td>2 to 4</td>
<td>Parallel Submission</td>
</tr>
<tr>
<td>Thailand</td>
<td>3 to 4</td>
<td>1 to 3</td>
<td>2 to 4</td>
<td>Sequential Submission; Central Government IRB</td>
</tr>
<tr>
<td>Indonesia</td>
<td>2 to 3</td>
<td>1-1.5</td>
<td>1 to 2</td>
<td>Sequential Submission</td>
</tr>
<tr>
<td>Vietnam</td>
<td>3 to 4</td>
<td>3</td>
<td>1</td>
<td>Sequential Submission</td>
</tr>
<tr>
<td>Hongkong</td>
<td>2 to 4</td>
<td>2 to 4</td>
<td>1 to 2</td>
<td>Parallel Submission; Cluster IRB</td>
</tr>
<tr>
<td>Taiwan</td>
<td>2 to 3</td>
<td>2 to 2.5</td>
<td>2 to 3</td>
<td>Parallel Submission; Joint IRB possible</td>
</tr>
</tbody>
</table>
Fig 7: No. of clinical trial certificates issued by regulatory agency (HSA), Singapore 2000-2011 as per trial phases \[^{[15]}\]

Fig 8: Number of Phase I-IV trials in SEA region \[^{[16]}\]
References

7. Siriporn Chawanon; Drug Control And Registration; [http://www.conceptfoundation.org/files/meeting/14.%20Chawanon%20-%20Drug%20Registration%20Thailand.pdf](http://www.conceptfoundation.org/files/meeting/14.%20Chawanon%20-%20Drug%20Registration%20Thailand.pdf)