## 1　Introduction

At ACUTA, we offer you something distinctive and unique. Along with our technology solutions offerings, we partner with our clients to achieve mutual success.  ACUTA Regulatory and Clinical Services (ARCS) experts are available to assist and work with you to create the optimum solution for your specific situation.  As an industry expert in regulatory submissions (both electronic and paper), ACUTA provides technical competency with industry recognized solutions plus extensive experience with large and small Life Sciences companies.

Our experienced ARCS team has the skills and technology to transform your paper-based submission into a fully compliant e-Submission.  Whether you need help transforming your legacy data to e-Submission format or assistance in compiling your e-Submission, our ARCS team is a very capable and efficient option.

## 2　Process

Our goal is to make your overall process easy, smooth, and efficient.  As important is to have access to your information from anywhere in the world 24x7.  The following figures illustrate how we begin and maintain your application(s) and submissions from start to end.

Figure 1 – Project Initiation
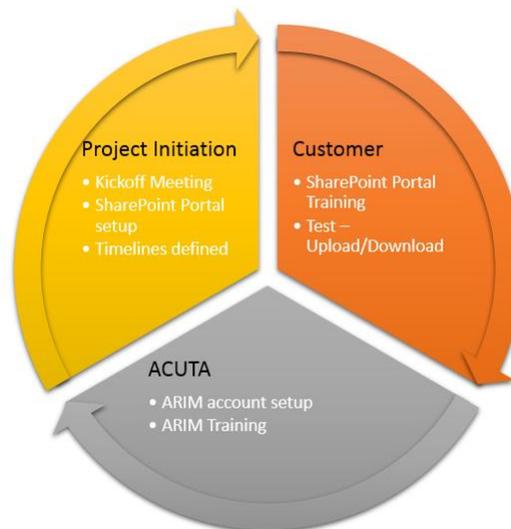


In the initiation phase, we create your portal in SharePoint, which is where we will keep documents that go into a submission.  The SharePoint portal is your dedicated site to manage your submission documents.  This site serves as your document management and collaboration center where multiple people from your organization contribute to the content you expect to include in a submission to an agency.

Also, in this phase we introduce our ARIM (ACUTA Regulatory Information management) System which will provide you access to all Applications/submissions that are in process as well as submitted to an agency.  Whenever you would like to view a document, submission, or entire application you will find them here.

Figure 2: Process/work-flow
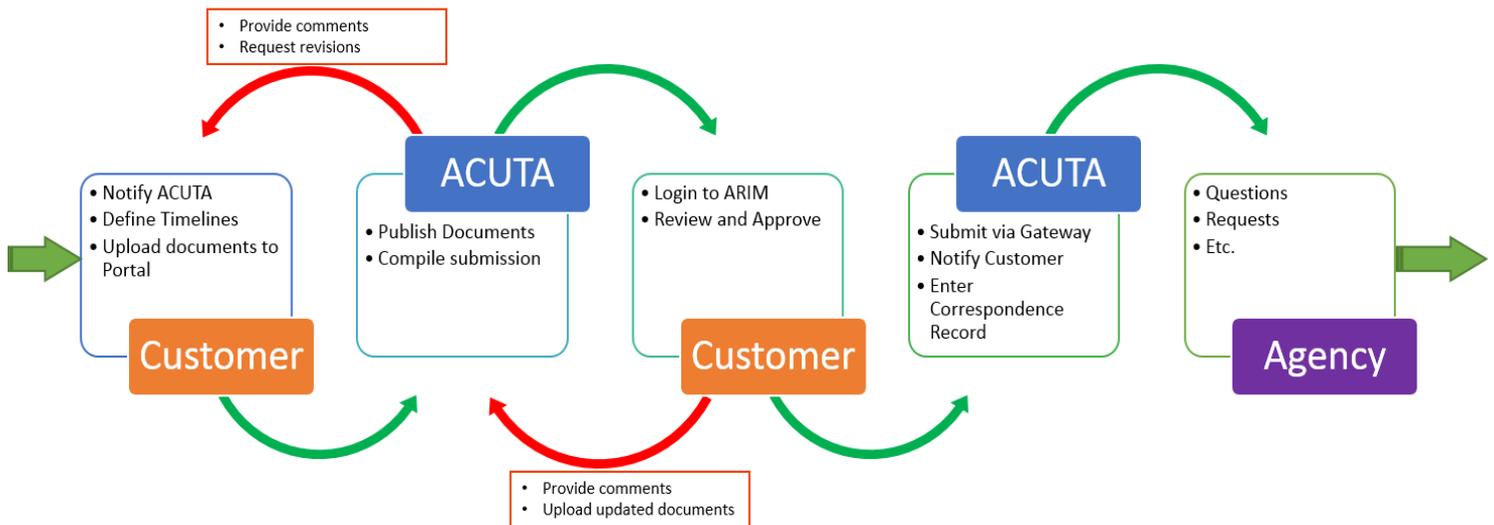


The above figure shows the overall process from start to end.  When you decide on a submission, you notify ACUTA and upload the documents to the SharePoint portal.  ACUTA, will process the documents and, if there are any issues, the ARCS team will inform you.  This process continues until all documents are pre-published and included in the submission.  When the submission is ready for your review and approval, an email notification will be sent to all assigned reviewers.  If there are any changes required by the reviewers, the ARCS team will update and re-publish the submission.  Upon your approval the submission will be sent to the agency via the appropriate gateway (or by mail to the agencies that do not have a gateway).  This cycle continues during an approval and post approval process.

Our ARIM system also has the capability to manage all your regulatory interactions (Correspondence and Commitments).  Please let us know if you are interested in using this capability.

## 3    Agreement

Our goal is to make the overall process simple while we continue to maintain a regulatory compliant process.  We use the same agreement process to assist you with your regulatory operations whether it is a one off engagement or an ongoing one to maintain your regulatory applications.

A Master Services Agreement (MSA) will be the first step of this process.  This agreement is a generic services agreement that allows you to engage ACUTA to assist you with any activity or project by placing a work order for each activity/project.  The MSA will include the pricing schedule, either on an hourly or daily basis, for various personnel within the ARCS team.  Typically this price will be fixed for up to 2 years.  When creating work orders we will use the same pricing.

The work orders will define the timelines, deliverables, and pricing for each activity and project.  ACUTA will invoice you once the deliverables are received and accepted by you.

## 4    Pricing schedule

At ACUTA we understand the various needs of customers regardless of their size.  We have defined a pricing structure which is very flexible, economical, and does not burden our customers.

## 4.1   Pricing for Standard and maintenance submissions

The time and cost to prepare a submission varies by the size of the submission and the time to prepare the documents and data for submission.  The amount of work ARCS has to spend in order to make the documents and data submission-ready is critical and drives the time and cost of the overall submission, in addition to the size of the submission.

In case of a **large submission**, until we receive the submission documents we will not know the time required to process them.  In this case, we create an estimate based on our past experience and input from your end, but keep an option to adjust the overall cost at a later time.  This will be a mutually agreed arrangement.

### *What do we need to prepare an estimate?*

| Module | Number. of Studies | Avg. no. of Documents | Format | Avg. no. of Pages | Comments |
|---|---|---|---|---|---|
| **Module 1** | n/a | | | | |
| **Module 2** | n/a | | | | |
| **Module 3** | n/a | | | | Indicate if you are providing granular documents or single files that require splitting. |
| **Module 4** | | | | | Avg. number of documents if granular (ICH E3) |
| **Data** | | | | | Number of datasets and standard (CDISC or legacy) |
| **Module 5** | | | | | Avg. number of documents if granular (ICH E3) |
| **Data** | | | | | Number of datasets per study (CDISC or legacy) |
| **CRF** | | | | | Number Per study |
| **Profiles** | | | | | Number Per study |
| **Other** | | | | | Indicate any specific agreements you have with FDA that is not part of typical submission |

**Format:**

**PDF**
PDF0 - Submission Ready PDF
PDF1 - Requires some cleanup
PDF2 - Requires republishing
**CRF**
CRF0 - Submission Ready
CRF1 - Requires by Domain of BM
CRF2 - Requires both Visit and Domain BMs

**Word**
Word0 - We structured and includes TOCs and Styles
Word1 - Requires some cleanup e.g. citations are not present
Word2 - Requires reformatting prior to PDF
**Data**
Data0 – Submission Ready CDISC or Legacy
Data1 – Requires define PDF/XML work

For **maintenance submissions**, we use a time and material based process.  You will be charged an hourly rate for a Senior and/or junior e-Submissions professional.  ACUTA will only bill for the actual time spent on each submission upon delivery.

## 5   Description of ARCS professionals

### 5.1.1   e-Submission Consultant/Expert

- Regulatory operations professional with over 10 to 12 years of regulatory submissions experience.
- Expert in e-submission business processes and technical areas.
- Available to assist/advise you on all aspects of regulatory submissions including pre-IND/NDA/BLA meetings, regulatory requirements related to eCTD, content placement, advice to authors on structure and technical aspects of submission documents.
- Expert level knowledge in clinical data requirements and clinical study report publishing.

### 5.1.2   Project Manager

- Manager or above level person with minimum of 5 years management experience.
- Experience with leading and mentoring a staff of Regulatory Operations publishers.

- Expert-level proficiency in all Regulatory Operations technologies, tools, and formats, including: eCTD, NeeS, and Paper formatted submissions.
- Expert in MS office, Acrobat, MS Project and other applications.
- Experienced project manager with excellent communication skills.
- High familiarity with relevant industry guidance and regulations and ability to ensure compliant submissions

### 5.1.3    e-Submissions Associate Sr.

- Regulatory operations professional with minimum 3 to 5 years' experience.
- Expert in eCTD, NeeS, and Paper submissions to multiple agencies around the world.
- Knowledgeable in multiple agency requirements and guidance for regulatory submissions.
- Expert in publishing for all types of submissions.
- Responsible to ensure all data for a submission are complete and are in compliance with agency guidelines and regulatory requirements, such as eCTD format and submission hierarchy.

### 5.1.4    e-Submissions Associate Jr.

- Junior regulatory operations professional with minimum 1 to 3 years' experience.
- Knowledgeable in eCTD, NeeS, and Paper submissions to multiple agencies around the world.
- Expert in pre-publishing process and formatting source documents (eg. Word).
- Responsible (under the supervision of senior associate) for preparing maintenance submissions such as investigator updates, safety reports, and annual reports, as well as assistance in preparation of amendments to both development and marketing applications.

## 6    Customer Quotes

| Response from a customer after delivery to FDA |
| --- |

**Subject:** RE: Sequence 00██ submitted to FDA!

Thank you ACUTA! I received a call from the FDA RPM at 6am this morning with questions on Serial 00██content! How wonderful to get almost instantaneous response/interaction because of the electronic submission!

Thank you!
Kika

Thanks ! Light speed. ☺

**From:** Shylendra Kumar [mailto:shy@acutallc.com]
**Sent:** Friday, February 13, 2015 5:56 AM
**To:** Charity
**Cc:** ACUTA Regulatory & Clinical Services
**Subject:** RE: ██████████ Submission 0002 is ready for Review and Signoff

Submitted!
Will send the acknowledgement later as I am at a meeting.

Shy