

Pioneering *Med*



eMed *Safety*

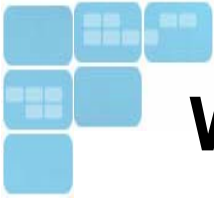
Product Introduction



Pioneering Med is a healthcare technology services company employing innovative techniques to streamline and automate currently manual medical processes.

PRIMARY FOCUS

- **Automate regulatory workflows**
- **Improve operational efficiencies**
- **Provide web-based cost effective services**



WHAT IS eMedSafety?



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PRODUCT OBJECTIVES

- Streamline clinical trials workflow
- Automate today's paper-based processes
- Focus on Adverse Event Reporting

PRODUCT OVERVIEW

- Software as a Service: SaaS
- Available on demand: 24 x 7
- Technology: Web based; Extensible; Scalable
- Customizable: Forms; Reports
- HIPPA Compliant: Security; Audit; Archival



HOW IT WORKS



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REGISTRATION

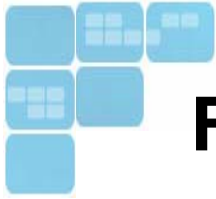
- Receive Start-up-Kit
- Complete business details
- Provide information on custom forms and reports

CONFIGURATION

- Manage Users / Roles
- Manage Sponsors / IRBs
- Manage Protocols / Drugs /Toxicities
- Approve custom forms / reports

ONGOING WORKFLOW

- Upload Safety Reports
- Upload Consent Forms
- Receive standard and custom reports
- Approve and Process



FEATURES



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CONTENT MANAGEMENT

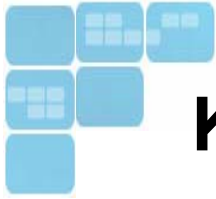
- Digitize and manage information
- Data Conversions using intelligent forms
- Search and archival capabilities
- Data versioning

FLEXIBLE OUTPUT

- Standard forms and reports
- Custom forms, reports, and summaries
- Data export to in-house systems

WORKGROUP AUTOMATION

- My Tasks
- Notifications and Alerts
- On-line signatures and approvals



KEY BENEFITS



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IMPROVED WORKFLOW

- **Timeliness: 24 hour turnaround**
- **Eliminate human error**
- **Search and archival capabilities**
- **Data versioning**

INFORMATION MANAGEMENT

- **High volume report handling**
- **Conversion to custom formats**
- **Audit trail of system access and data modifications**
- **Maintenance of historical records**

REGULATORY COMPLIANCE

- **IRB reporting**
- **FDA reporting**
- **Reporting as per protocol / sponsor guidelines**



Process



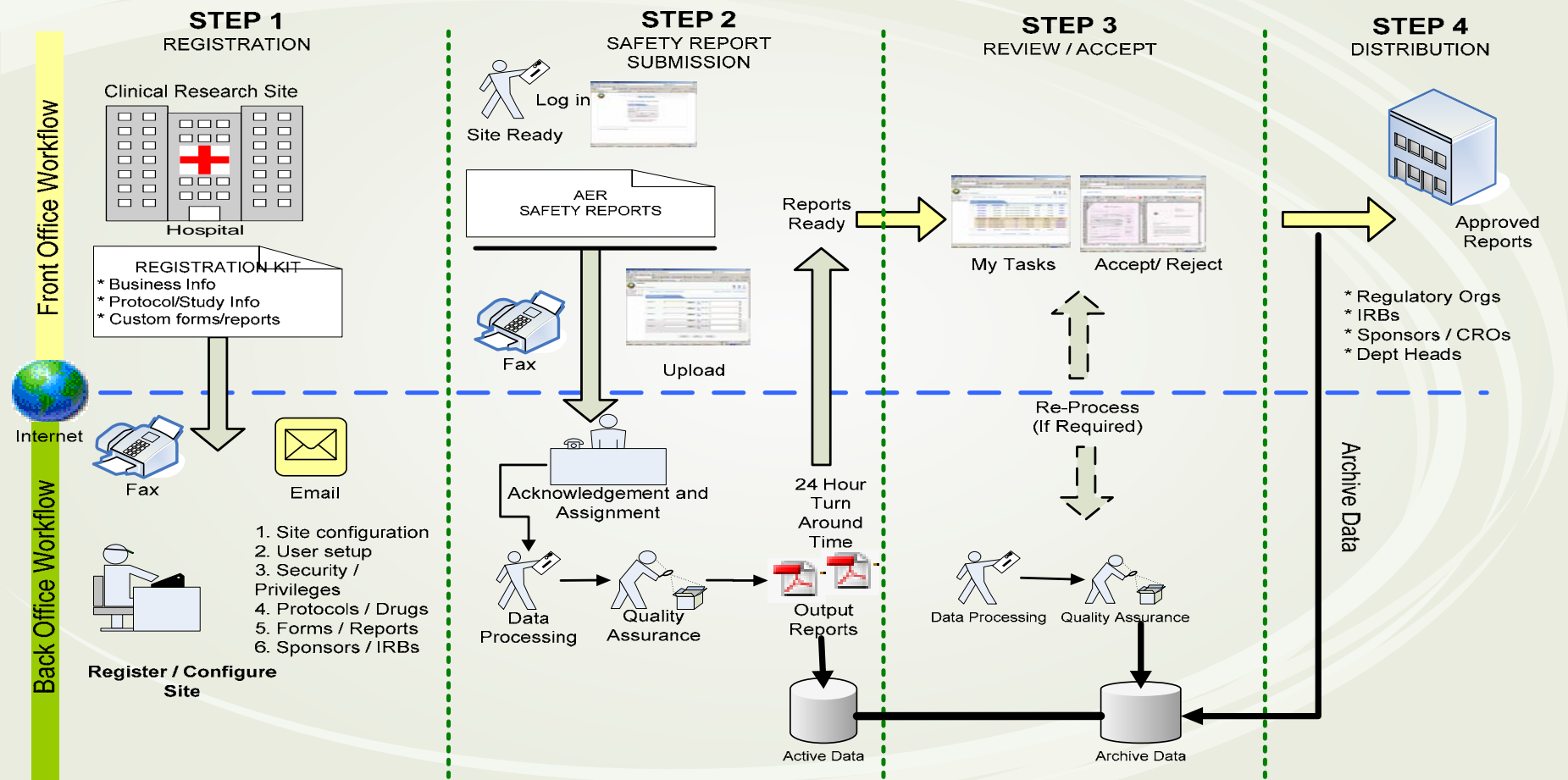
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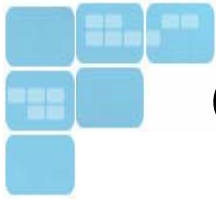
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Workflow Process Diagram

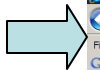




Clinical Site - Workflow



Step 1
Log On



Step 2
Upload



Step 3
My Task



Step 4
Accept Reports



The screenshot displays a multi-step workflow in Internet Explorer. The first window shows the 'Sign Up' page. The second window shows the 'Upload Safety Report' page. The third window shows the 'My Tasks' page. The fourth and largest window shows the 'Compare Reports' page, which contains a detailed form for 'SUSPECT ADVERSE REACTION REPORT' and a 'Safety Investigator Report' from Pfizer Global Pharmaceuticals. The form includes fields for patient information, medication, and adverse reaction details. The report text discusses guidelines for clinical trials and provides contact information for Pfizer.



Back Office - Workflow



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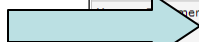
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Step 1
Manage Customers

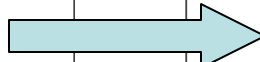


The screenshot displays a multi-windowed desktop environment. The top window is titled 'New Customer - Windows Internet Explorer' with the URL 'http://203.196.141.195/emedafety/newCustomerTemp.do'. Below it is another browser window titled 'New Protocol - Windows Internet Explorer' with the URL 'http://203.196.141.195/emedafety/PopProtocol.do'. A third browser window is titled 'Master Form - Windows Internet Explorer' with the URL 'http://203.196.141.195/emedafety/newMasterFormTemp.do'. The main browser window is titled 'Safety Report Details - Windows Internet Explorer' with the URL 'http://203.196.141.195/emedafety/jsp/SafetyReportDetail.jsp?srNo=SR07000100&status=Uploaded'. This window shows a 'Safety Report Details' form with fields for 'Safety Report Description' (Suspect Adverse Reaction Report) and 'Current Status' (Uploaded). A table below shows the status history with columns for 'Status' and 'Status Date', containing one entry: 'Uploaded' on '04/27/2007'. To the left of the browser windows is a vertical navigation menu with items such as 'My Homepage', 'My Account', 'Manage Sponsors', 'Manage IRBs', 'Manage Drugs', 'Manage Protocols', 'Manage Users', 'Manage Forms', 'Manage Reports', 'Audit Trail', 'System Configuration', 'Manage Site', 'Manage Spon', 'Manage IRBs', 'Manage Drug', 'Manage Proto', 'Manage Cus', 'Manage Users', 'Manage Form', 'Manage Repo', 'Audit Trail', and 'System Conf'. At the bottom of the screen, an Adobe Reader window is open, displaying a 'SUSPECT ADVERSE REACTION REPORT' form from Bristol-Myers Squibb Company. The form includes a header with the company logo and name, and a section titled '1. REACTION INFORMATION' with fields for patient ID, country, date of birth, age, sex, reaction onset, and check all. The taskbar at the bottom shows the Start button and several open applications including Internet Explorer, Skype, Microsoft Word, Microsoft Excel, and eMed_Road...

Step 2
Manage Protocol

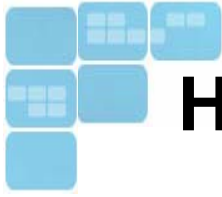


Step 3
Manage Forms & Reports



Step 4
Notify Clinical Site





How to start...



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3- Step to go live

- 1 Sign Up**
 - Simple Subscription Agreement
 - Provide “ Start up Information”

- 2 One Hour Web Training for your users**
 - Identify Users
 - Go through Personalized Training Program
 - Online evaluation and User Certification

- 3 Ready with the system:**
 - Receive the start up access ids
 - Ready to start...



Up in less than 1 day!



Road Ahead



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PHASED RELEASE

- Release 1: External AEs (2Q08)
- Release 2: Internal AEs and Site-IRB-Sponsor workflow
- Release 3: Sponsors and CROs
- Release 4: Data and Statistical Services

STRATEGY

- Provide Business Value with each release
- Use customer feedback to define next release