



Electronic Data Capture system (ez-EDC) developed by Alpha Clinical Systems in collaboration with USA based CRO, helps in streamlining the clinical data collection and effectively monitoring the sites to verify the accuracy and quality of the collected data.

- **Streamlined Site Data Collection and Management**

Alpha Clinical System's ez-EDC Remote Data Entry enables study sites to enter and manage their own CRFs, run reports and view study documents. Our ez-CRF reduces process and administration time for clinical staff, maintain process and data integrity and simultaneously create efficiencies for Site Staff.

- **Improved Site communications and collaboration**

Our ez-EDC/ez-CTMS systems facilitate a virtual meeting place and collaboration environment for both Sponsor and Site Staff. Site staff can upload / share documents through ez-EDC/ ez-CTMS systems with Sponsor Staff; Monitors can post study specific information, or send messages to Site Staff or use automatic reminders to notify Site Staff.

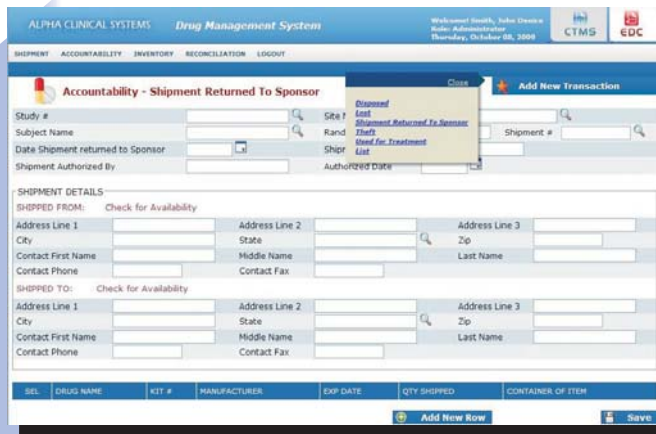
- **Role based Security**

Users are given access to the system based on their roles and studies assigned to them. Only authorized users can view/edit/modify the CRF data, resolve the queries.

- **Reduced data closure time**

Site Staff has access to their data on-line, enabling them to manage data quality and conduct data corrections. Site Monitors can track upcoming critical events and dates.





○ **Data integrity**

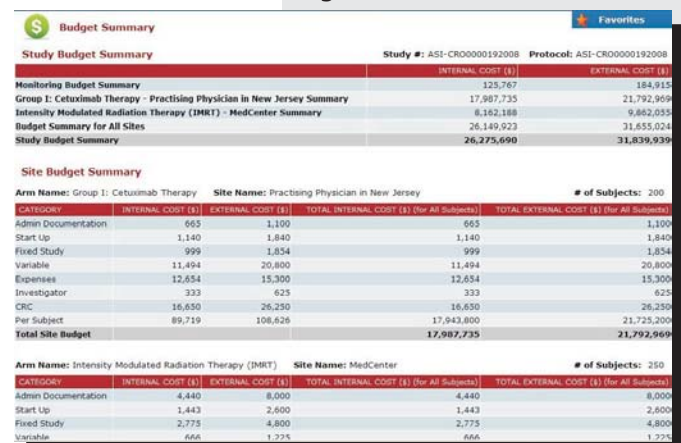
By integrating all of the trial processes into an integrated system (ez-EDC and ez-CTMS), Alpha Clinical Systems provide a seamless environment for clinical trial management. Providing support for 21 CFR Part 11, our systems are developed to meet all FDA guidelines for clinical data management systems.

Key Features:

- Ease of creating CRFs for any study within no time with our Form Builder
- Supports versioning of CRFs. You still have old version CRFs for already completed visits
- Ability to map individual forms of CRF module to different Visits based on protocol requirements
- Intuitive Flagging of all queries on the CRFs
- Managing field or form level queries and the changes in the CRF data
- Separate workflow for capturing the Adverse Events and Serious Adverse Events as per the IRB/IEC requirements
- Integrated Drug Tracking and Management with Accountability, Inventory and Reconciliation features
- Creating and modifying Monitoring Plans for seamless monitoring

Integration with ez-CTMS

Our ez-EDC integrates with our ez-CTMS seamlessly providing a complete suite of Clinical Trial Management. All users of the Study Protocol can access the data across systems securely and efficiently avoiding other modes of communication thus reducing operational costs and expediting the time to market.



Study Budget Summary		INTERNAL COST (\$)	EXTERNAL COST (\$)
Monitoring Budget Summary		125,767	184,915
Group 1: Cetuximab Therapy - Practising Physician in New Jersey Summary		17,987,735	21,792,969
Intensify Modulated Radiation Therapy (IMRT) - MedCenter Summary		8,182,188	9,882,055
Budget Summary for All Sites		26,149,923	31,655,024
Study Budget Summary		26,275,690	31,839,939

Site Budget Summary		INTERNAL COST (\$)	EXTERNAL COST (\$)	TOTAL INTERNAL COST (\$) (for All Subjects)	TOTAL EXTERNAL COST (\$) (for All Subjects)
Arm Name: Group 1: Cetuximab Therapy	Site Name: Practising Physician in New Jersey				# of Subjects: 200
Admin Documentation		655	1,100	655	1,100
Start Up		1,140	1,840	1,140	1,840
Fixed Study		999	1,854	999	1,854
Variable		11,494	20,800	11,494	20,800
Expenses		12,654	15,300	12,654	15,300
Investigator		333	625	333	625
CRF		16,650	26,250	16,650	26,250
Per Subject		89,719	108,628	17,943,800	21,725,200
Total Site Budget		17,987,735	21,792,969		

Site Budget Summary		INTERNAL COST (\$)	EXTERNAL COST (\$)	TOTAL INTERNAL COST (\$) (for All Subjects)	TOTAL EXTERNAL COST (\$) (for All Subjects)
Arm Name: Intensify Modulated Radiation Therapy (IMRT)	Site Name: MedCenter				# of Subjects: 250
Admin Documentation		4,440	8,000	4,440	8,000
Start Up		1,443	2,600	1,443	2,600
Fixed Study		2,775	4,800	2,775	4,800
Variable		666	1,325	666	1,325