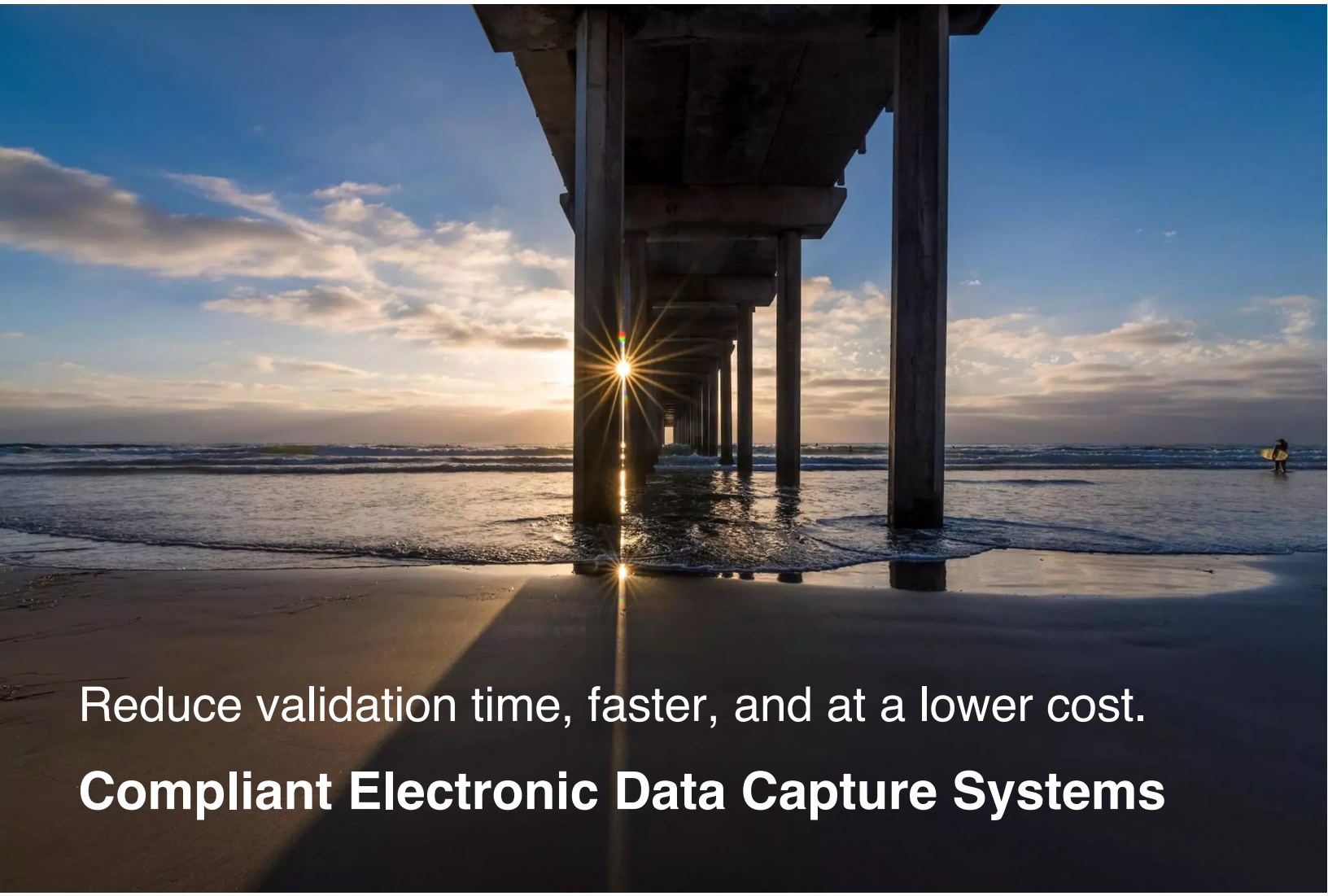
UC San Diego
SANFORD STEM CELL INSTITUTE
Sanford Stem Cell Clinical Center

CIRM ALPHA CLINICS NETWORK

UC San Diego Health



Reduce validation time, faster, and at a lower cost.

Compliant Electronic Data Capture Systems

Trust your electronic system validation with the academic partner from start to finish.

Laboratory, manufacturing, and quality workflows that follow industry good practice (GxP) guidance protocols and/or Good Automated Manufacturing Practice (GAMP™) require validation of computer systems. This can include compliance to 21 CFR Part 11, Annex 11, or similar local regulations, standards, or guidance for data integrity of electronic data records. Validating computer systems helps ensure that complete, accurate, reliable, consistent, secure, and reproducible electronic data records are readily available to users.

Our Alpha Clinic Data Management Core (ADRC) provides comprehensive and flexible audit-ready documentation packages that help you reduce risk and comply with regulations and standards. Our core can help save you valuable time and costs because we are a nonprofit, aligned first in the spirit of discovery and second in that we cannot charge a premium.

10+ Years of Regenerative Medicine Excellence

We have two product lines and are flexible in meeting the needs of customized requests.

Documents and services included	Base	Plus
Validation plan		●
Validation risk analysis (RA)		●
User requirements specification (URS)		●
System configuration specification (SCS)	●	●
Validation test plan		●
Software installation qualification (IQ) with objective evidence	●	●
Software operational qualification (OQ) with objective evidence	●	●
Software performance qualification (PQ) with objective evidence		●
Traceability matrix		●
21 CFR Part 11/Annex 11/GAMP5 assessment		●
Quality assurance review		●
Validation summary report		●
Document customization support Template only Template only		●
Full validation support		●
End-to-end project management and execution support		●

Add-on services available with additional charges	Base	Plus
Execution add-on		●
Document add-on	●	●
Expedited documentation add-on	●	●
Custom request (including revalidation)	*Request a quote*	

We offer other services and products:

Raising funds for your project

Pre-clinical and Clinical Trial Design

Pre-clinical and Clinical Trial Execution

Cell-Therapy Clinical Service

FDA Regulatory Management – IND/IDE

GMP Cell and Gene Manufacturing

Venture Development

Education and Training Opportunities

Contact: AlphaStemCellClinic@Health.UCSD.edu