



Trial Initiation  
Design



Programming and  
Development



Printing and  
Management



Deployment



Trial Management  
and Support



Trial  
Completion

# ADVANCED DIGITAL PEN & PAPER

ADPP uses a smart ballpoint pen containing a tiny camera, processor, memory and datalink in conjunction with ordinary paper overprinted with an almost invisible dot pattern, which the camera reads.

The digital pen produces a traditional paper record whilst faithfully recording every pen stroke, together with its precise time and date, as the user fills in a form or makes notes in a daybook. When the user has finished writing, the data in the pen's memory is uploaded to a computer system by docking or via mobile phone. The system stores a record of all the pen strokes (including their time and date stamps) and creates an image of the paper document. Handwriting is automatically converted to XML ready for verification, validation and subsequent output to the clinical data management system.

The Trialscribe ADPP solution has a number of unique features ideally suited to the clinical investigations environment:

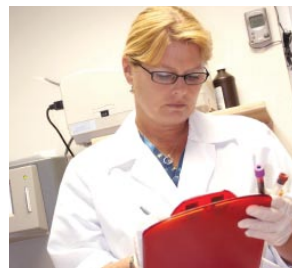
- The system provides complete data security and integrity from the pen to the data archive.
- The solution applies a unique dot pattern to every CRF or notebook page for the pen to read. With the pattern on no two pages alike, and every page identifiable by the computer system which produced the pattern, complete historic traceability is readily achieved.
- The form printing process includes the ability to pre-fill digital forms with subject data from clinical trials management systems, further enhancing data quality and making life easier for the user.

The digital pen solution is convenient, simple to use, easy to deploy and gets data back for analysis in real time.



# DELIVERING BENEFITS AT EACH STAGE OF THE PROCESS

Key Benefits		ADPP Solution
1	Data Integrity and Regulatory Compliance – the security features built into the ADPP system ensure that there is complete and persistent traceability of the sequenced completion of a CRF or patient diary.	✓
2	Traceability – a faithful electronic image of each completed clinical report form (CRF) is retained within the ADPP system.	✓
3	Reduced CRF Processing and Handling Costs – data is uploaded directly from the digital pen. Handwriting is automatically converted to machine readable data which requires verification only, eliminating labour intensive data extraction and scanning.	✓
4	Real Time Information – clinical data is available for analysis immediately the pen data is uploaded and verified – enhancing trial efficiency and increasing speed to market.	✓
5	Data Quality – completion rules and logic can be built in to each CRF to ensure completion of key data fields at point of capture.	✓
6	Data Pre-filling enables personalisation of CRFs (e.g. with patient or investigator details) reducing data capture requirements and improving data quality at point of capture.	✓
7	Low Training Costs – a digital pen user requires very little training.	✓
8	Low User Support Costs – a digital pen requires low levels of support.	✓
9	High Investigator Satisfaction – many investigators are more comfortable with a pen than with a PC.	✓
10	Record of Last Resort – the physical paper document is always available as a record of last resort.	✓



# ENHANCE YOUR CLINICAL STUDIES WITH ADPP

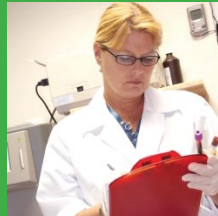
Trialscribe addresses the requirements for secure, traceable data capture and processing efficiency in clinical investigations.

An Advanced Digital Pen & Paper (ADPP) solution, Trialscribe combines the traditional convenience, security and traceability of the paper based approach with the data processing and speed to market benefits of Electronic Data Capture (EDC).

Trialscribe ADPP uses an electronic ballpoint pen, producing a traditional paper record whilst faithfully recording every pen stroke as the user fills out a CRF form, patient diary or makes notes in a daybook. When the user has finished writing, the data in the pen's memory is uploaded to a computer system, creating a record of all the pen strokes plus an image of the paper document. Handwriting is automatically converted to XML ready for validation and analysis.

The digital pen is convenient, simple to use and low maintenance. Trial efficiency is enhanced because data is available for validation and analysis immediately it is uploaded.

The Trialscribe ADPP system is secure, data is fully traceable back to its source and meets the regulatory guidelines for clinical data capture (21CFR Part 11).



# TRIALSCRIBE – A COMPLETE SERVICE

The Trialscribe Advanced Digital Pen and Paper solution is a collaborative development for the pharmaceutical industry by Greens Digital, Digital Field Solutions and Data Magik. This collaboration brings together the full range of essential, complementary, skills required to deliver a complete clinical investigation solution:

- **Greens Digital** – experts in the design, printing and management of clinical data capture forms and documents.
- **Data Magik** – experts in trial design, data management and statistical analysis.
- **Digital Field Solutions** – experts in the development and deployment of Advanced Digital Pen & Paper solutions.

Our knowledge and experience of all aspects of clinical investigations combined with our expertise in Advanced Digital Pen & Paper and data management systems means that we can customise and deliver solutions to meet your exact requirements.

For more information on how we can help you enhance your clinical investigation programmes please contact:

Tel: 01494 834900  
Email: [solutions@trialscribe.co.uk](mailto:solutions@trialscribe.co.uk)  
Web: [www.trialscribe.co.uk](http://www.trialscribe.co.uk)

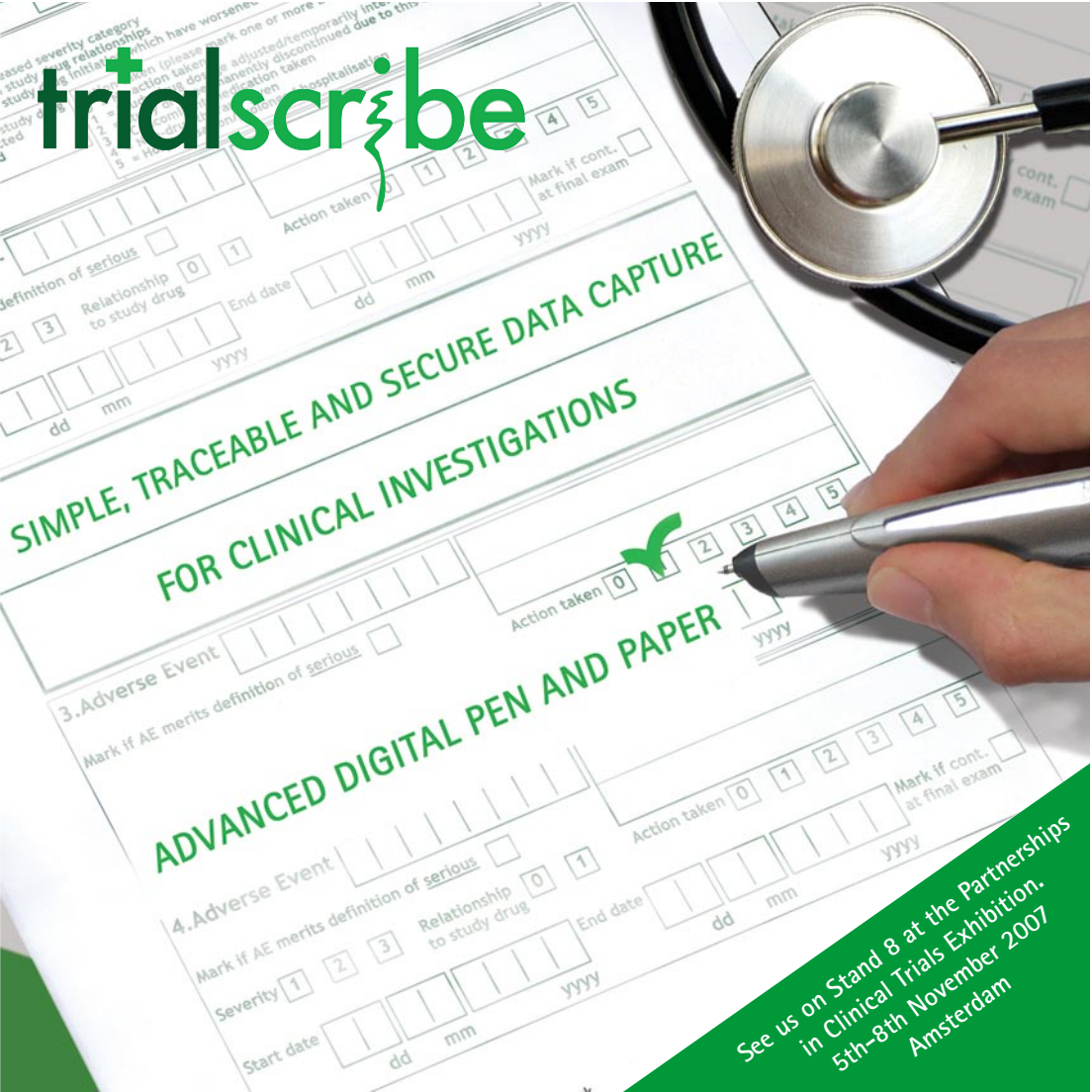


**TRIALSCRIBE – EXPERIENCE MATTERS**

# trialscribe

**SIMPLE, TRACEABLE AND SECURE DATA CAPTURE  
FOR CLINICAL INVESTIGATIONS**

**ADVANCED DIGITAL PEN AND PAPER**



See us on Stand 8 at the Partnerships  
in Clinical Trials Exhibition,  
5th-8th November 2007  
Amsterdam