

CLINICAL

Concept

Time is money. **AKAS** Clinical from 4th Wave Technologies is a cutting edge solution that creates and administers clinical trials over the Internet, saving time, effort and expense. Customers benefit from controlled trial cost, improved data quality and reduced time to market.

The concept is simple. Instead of relying on mountains of paper **AKAS** trials are administered electronically via the Internet. Doctors taking part input their findings directly into a central database via a series of intelligent web based forms. All data is verified and validated as it is entered.

Naturally this means that administrators can review the progress of the trial at any time. Trends are instantly visible, unexpected results easily recognised. The system always displays the latest

information. The database is a “clean” record of the trial and can knock weeks or even months off of a development cycle.

And it’s easy to set-up to. The Windows based Builder application makes administration a breeze. Software Wizards guide the Administrator through the creation process, building the relevant forms and databases automatically. Complex trial protocols can be implemented in hours, without any knowledge of databases or programming. **AKAS** does all the work.

AKAS Clinical is a member of 4th Waves’ “Advanced Knowledge Acquisition System” family of products. It takes the clinical trials process into the twenty-first century with a solution that is powerful, flexible and easy to use.

User Experience

The Trial Builder

The heart of **AKAS** Clinical is the Trial Builder, an easy-to-use Windows application.

Once the protocol has been finalised the builder is used to create an **AKAS** Trial. Each trial consists of a number of forms, not unlike those used in the traditional process. Like paper forms these also contain spaces (fields) into which data will be entered. However here the similarity ends because **AKAS** forms are intelligent.

At its most fundamental this “intelligence” is simple validation. Each field has rules that govern what type of data is recognised as valid. [more >>](#)

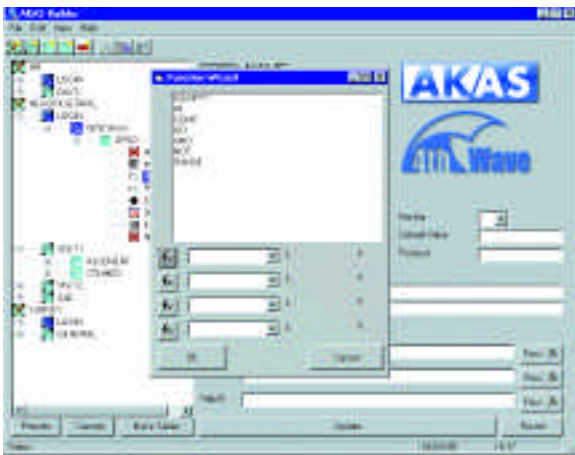


AKAS Trial Builder Screenshot



User Experience

For example in a trial targeted at children an “Age” field would only accept numbers between “0” and “17”. The entry of a figure outside this range would trigger a request for clarification.



AKAS Trial Builder Rules Wizard

The builder includes software Wizards that allow the setting of extensive and flexible validation rules across a wide range of criteria. Form fields know the type of data that they require, but that isn't all. Fields can also affect one another. For example the “Age” field can alter the rules applying to a later field such as “Height”. Imagine, for example, that we were building a trial to test the effects of a drug on the growth of young children. In this study age is related to height. An older child might have to be particularly small to qualify under the protocol. This requirement could be easily integrated into the trial using the supplied software Wizards. Finally the “intelligence” is present at form level. Like fields, each form is easily associated with a specific set of rules. These can alter the behaviour

of the form, or decide whether it is shown at all. For example, in some tests the gender of a subject might preclude certain questions and trigger others. The order in which the forms are presented can be fully automated. Trial Investigators or monitors can be guided through the process seeing only the questions relevant to their subject.

Although the use of field and form rules is very easy they can combine in very powerful ways. A well designed trial will limit the possibility of incorrect data being submitted, support the end user through ongoing validation, and customise the trial for certain types of subjects.

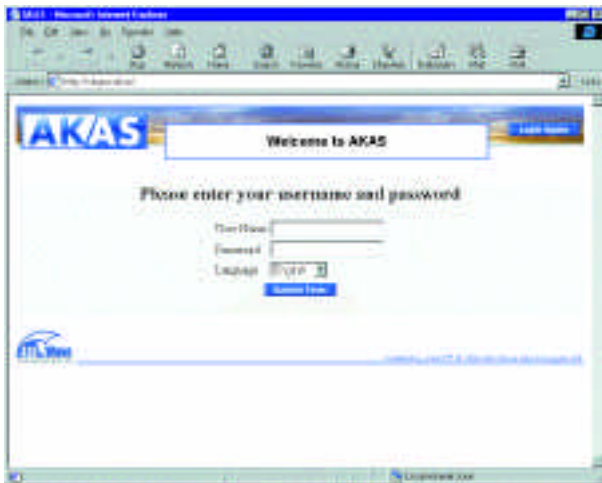


AKAS Trial Builder Screenshots

All this can be achieved very rapidly with no knowledge of databases or programming. The user-friendly **AKAS** Builder allows complex trials to be developed and tested in a matter of hours. Once the trial is ready the Administrator simply pushes the build button. **AKAS** then creates the web-forms and related databases automatically. It could not be simpler.

End User Experience

Participating doctors simply log onto **AKAS** via a secure Internet connection.



Trial Logon screen

Once the system verifies their identity they have access to all the forms designed for that trial. They simply fill them in as they would normally fill in paper forms... well almost.

The fact is that an **AKAS** trial is far easier to use than any paper-based system. Users are supported

by instant feedback. Mistakes or omissions are caught before they are uploaded. Context sensitive forms request only information that is specifically required.

In addition **AKAS** supports each type of user as appropriate. The doctors investigating patients follow a guided process that includes context sensitive help information directly from the trial protocol.

Similarly **AKAS'** live data can provide inputs for all common project management systems, providing real-time feedback to them at every stage. Trial monitors have access to all the information in an easy to use format that allows each response to be positively vetted. Suspect responses are highlighted for easy reference, and communication back to the investigator is automatic.

Once all the protocol requirements have been met the system automatically submits the information to the database, where it is collated and stored. There is no pile of paper to lose or spill coffee over. The trial can simply be put to one side... until the next time.

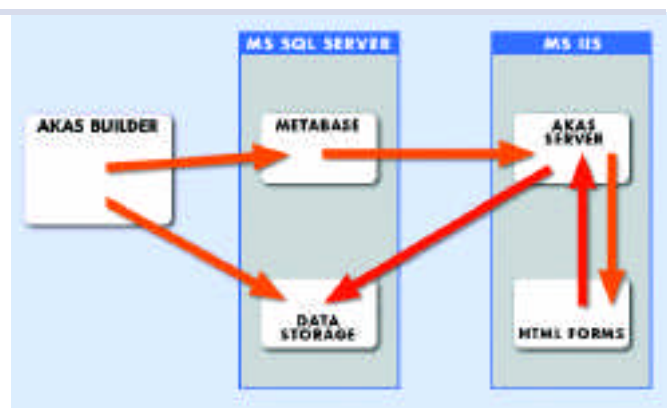
Technology Briefing

Technical Implementation

AKAS integrates the bespoke Builder application into a Microsoft SQL Server and a Microsoft Internet Information Server, both running on a Windows NT platform. The SQL Server is secured behind a firewall. (See diagram opposite).

Users access a particular trial over the Internet through a standard Web browser.

[more >>](#)



Technology Briefing

The Web server uses third party authenticated secure sockets layer (SSL) to verify connection to the correct server. Consequently, the server must be registered with a trusted third party authentication service such as Verisign.

The SQL Server stores the **AKAS** Clinical metabase describing the trial details. The metabase is created and maintained by **AKAS** Builder.

The SQL Server also contains the trial database and the audit trail. Here all the clinical data is collected, monitored, and amended. The data can be analysed in situ, or exported to the sponsor's chosen format, such as SAP R3.

System Requirements

AKAS system requirements can be divided into three separate areas, Builder, User and Manager.

Builders of **AKAS** Clinical trials require a PC with Windows NT workstation, Internet access and a networked connection to an **AKAS** enabled SQL Server. A minimally functional Windows NT platform

will operate with **AKAS**, but we recommend a system with a minimum of 128 Megabytes of memory and a large display screen.

Users of **AKAS** Clinical need an Internet enabled PC running a web browser such as Microsoft Internet Explorer or Netscape Navigator. Alternatively 4th Wave's QuickNet PB is a low cost personal browser system designed to deliver secure access to dedicated Internet applications.

The backend **AKAS** Manager system requires a dedicated Windows NT server running Microsoft SQL Server and Microsoft Internet Information Server. The IIS must run in secure sockets layer. The system must have access to the Internet. The SQL Server must be secured behind a suitable firewall. Multiple trials can be run from the same servers. Multiple sponsors can share the same server resources, since each trial authenticates its own users.

If required 4th Wave Technologies can provide the equipment and technical expertise to support your **AKAS** roll-out.

SECURITY

Over the last twelve months Internet Security standards have become the most stringent of any implemented on electronic systems. The standard level of security required by the FDA is implemented on AKAS as standard. Increased security can be implemented if required. 4th Wave recommends the use of a three layered security strategy for AKAS Clinical. We use encrypted transmissions over the Internet, third party authentication of each server system, and digital signatures for each user.

DEPLOYMENT

Initially AKAS Clinical will be deployed as a service. 4th Wave will develop and host clinical trial applications as a service for pharmaceutical companies. As the system develops it may also be offered as a turnkey solution, including all necessary hardware and technical support, and with systems management training.

THE FUTURE

AKAS Clinical is ready now. Contact 4th Wave for a presentation and demonstration. Today, AKAS delivers a clean database in the shortest time for further clinical research work. Future releases will concentrate on strengthening further the project management aspects of the system, and building enhanced facilities for researchers and regulators to analyse the data and investigate anomalies.



If you are interested in learning more about AKAS Clinical or future implementations of the ADVANCED KNOWLEDGE ACQUISITION SYSTEM please contact Sam Scoggins at this address:

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