StudyBuilder ™

Study design and data management software for audit, clinical trials, diaries, registries and patient management

NEW
UNLIMITED SITES
No extra per site fees when collecting study data

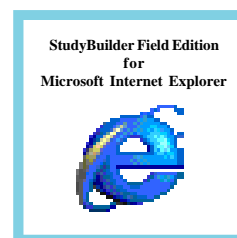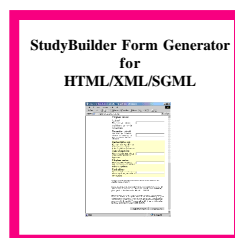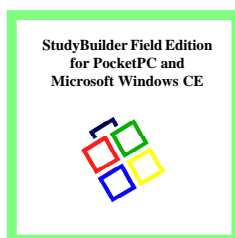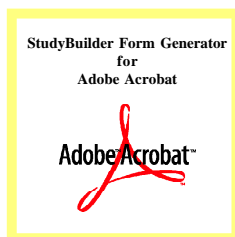StudyBuilder Field Edition for Microsoft Windows 95/98/2000/ME/NT

StudyBuilder Form Generator for Microsoft Word 95/97/2000 and Rich Text Format

StudyBuilder Field Edition with Direct Device Data Download

Microsoft Windows for Wor...

StudyBuilder Field Edition for Apple Mac OS

StudyBuilder Field Edition for Games Consoles

StudyBuilder Form Generator for Adobe Acrobat

StudyBuilder Field Edition for Linux OS

StudyBuilder Field Edition for PocketPC and Microsoft Windows CE

StudyBuilder Form Generator for HTML/XML/SGML

StudyBuilder Field Edition for Microsoft Internet Explorer

StudyBuilder Field Edition for Palm Computing Platform

How do you want to collect your data today?
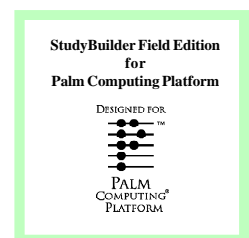
StudyBuilder 2005
Information Kit

Build Study...

The data collection tool for medical research

Products
- STUDYBUILDER PROFESSIONAL EDITION
- STUDYBUILDER ENTERPRISE EDITION
- STUDYBUILDER FIELD EDITION
- INTERNET SERVERS
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- UPGRADES
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- WHY USE STUDYBUILDER?

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- SUPPORT DETAILS
- FREQUENTLY ASKED QUESTIONS

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- ORDER FORMS (EUR, GBP, USD, JPY)

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- EXTRACT FROM 'INSIDE STUDYBUILDER'

Quick start
- EXECUTIVE SUMMARY
- CONTACT DETAILS

StudyBuilder Professional Edition

Just $1,499 / €1,499 / £999 / ¥149,000

ISBN-1-904694-51-9
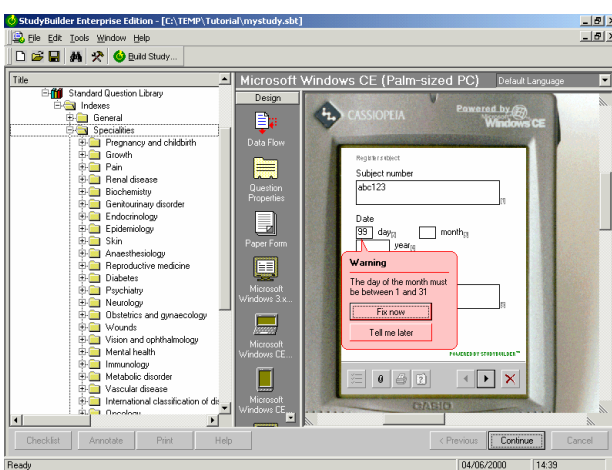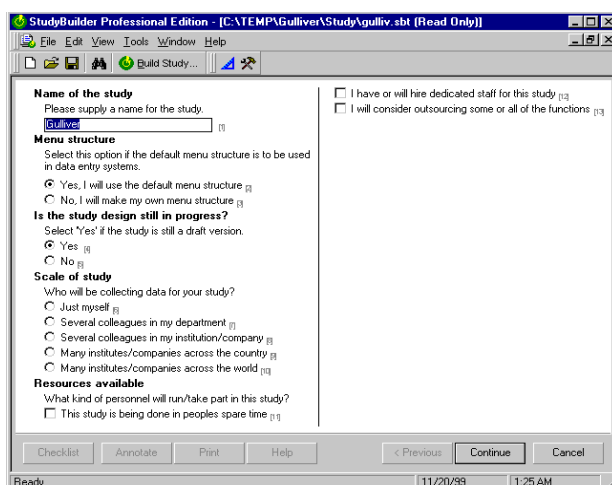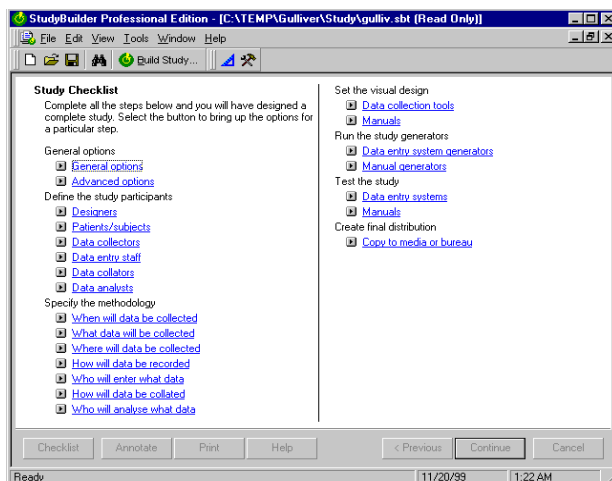
StudyBuilder Professional Edition provides the ability to design and manage audits, clinical trials, registries and other medical studies. The software runs on computers running Microsoft Windows 95/ 98/ 2000/ 2003/ ME/ NT / Tablet PC/ XP.

Properties of the study such as how many subjects will take part, which hospitals will participate etc. are collected by simple use of 'Wizards'. The study checklist allows users to see how for through the complete study design process they are at any time.

When you need to select questions, the screen appears similar in layout to Windows Explorer in which your monitor screen is divided into a left side – the validated question library, and a right side - your interactive WYSIWYG (what you see is what you get) preview of the study materials.

A study is easily designed by dragging your own questions, or questions from our extensive library of validated questions, and dropping them into your study materials. You can instantly see what the materials (paper forms, computer databases, study manuals and protocols) which will actually be used to collect the study information will look like.

To place an order or to learn more about StudyBuilder products contact your nearest office today

An experienced user can design a study in less than a day. However, as study design is a process of continuous refinement we expect most users to spend a few weeks on and off building the first version of their study, returning every month or two to incorporate feedback and refinements suggested by the study users. Only StudyBuilder makes this practical.

Once the study design is complete, pressing the 'build study' button automatically builds all the study materials: paper forms, computer databases, study manuals and protocols. If the study is to be deployed in several countries, the software can use professionally validated translations to produce the materials in the appropriate languages. Currently more than 80 languages are supported with other languages available on request.

StudyBuilder Professional Edition uses our extensive library of validated study questions. We continuously monitor the scientific literature to ensure that its question libraries are current and relevant. A rigorous peer reviewed testing process ensures that the questions are of the highest quality. These questions are then translated and further validated by specialist personnel.

StudyBuilder Professional Edition includes StudyBuilder Field Edition for Microsoft Windows 95/ 98/ 2000/ 2003/ CE/ Mobile/ ME/ NT/ Pocket PC/ Tablet PC/ XP and Apple Mac OS. Registered users can download updated question libraries and software for twelve months after purchase of a qualifying product.

Afrikaans, Azərbaycan-ılı, Bahasa Indonesia, Bahasa Malaysia, Català, Čeština, Cymraeg, Dansk, Deutsch, Eesti, English (United Kingdom), English (United States), Español, Euskara, Føroyskt, Français, Galego, Hrvatski, isiZulu, Íslenska, Italiano, Kiswahili, Latviešu, Lietuvių, Magyar, Nederlands, Norsk, Polski, Português, Qheshwa, Română, Shqipe, Slovenčina, Slovenski, Srpski, Suomi, Svenska, Tiếng Việt Nam, Türkçe, Uzbek, Ελληνικά, Азәрбајчан, Беларускі, български, Қазақ, Кыргыз, Монгол хэл, Русский, српски, Татар, україныска, Ўзбек, Հայերեն.

עברית, اردو, فارسى, عربية, कोंकणी, मराठी, संस्कृत, हिंदी, ਪੰਜਾਬੀ, ગુજરાતી, தமிழ், తెలుగు, ಕನ್ನಡ, ไทย, ქართული, മലയാളം, 中文(简体), 中文(繁體), 한국어, 日本語

StudyBuilder Enterprise Edition   **Just $4,999 / €4,999 / £2,999 / ¥499,000**

ISBN-1-904694-52-7

StudyBuilder Enterprise Edition is for groups of study designers who wish to work on the same study simultaneously, build custom question and/or study libraries or integrate data collection tools into existing systems. The software runs on computers running Microsoft Windows 95/ 98/ 2000/ 2003/ ME/ NT/ Tablet PC/ XP.

StudyBuilder Enterprise Edition has all the features of StudyBuilder Professional Edition plus additional tools for groups. Collaboration over networks and email systems makes it possible for locally and internationally distributed study design teams to work together. Data can be collected via Web sites and warehoused on systems such as Oracle and Microsoft SQL Server or the supplied database system.

StudyBuilder Enterprise Edition allows the creation, management and distribution of custom question and study libraries. Access can be granted to certain libraries so that only qualified users have permission to use them. Studies and libraries can be published in 'review only' mode (users can see the study design and materials but not edit or use them), read only mode (users can use study designs but not change them) or full mode (users can use and modify). These permissions can be applied to whole or specific portions of the libraries.

This product also contains special versions of StudyBuilder Field Edition that can be embedded into packages such as Microsoft Access or Corel Paradox for quick and simple data entry form design. Alternatively, StudyBuilder Field Edition subsystems such as the cross platform database engine, secure data transport or data validation engine can be integrated into custom software royalty free.

StudyBuilder Field Edition

Free[1]!

StudyBuilder Field Edition is the royalty free data collection tool deployed and used by investigators and subjects to provide study data. The software runs on desktop computers (Microsoft Windows 3.1/ 95/ 98/ 2000/ 2003/ ME/ NT/ Tablet PC/ XP, Linux OS, Mac OS and web browsers), palmtops (Palm OS, Psion, Symbian OS, Windows CE/Mobile/PocketPC), smart mobile phones and games consoles.

StudyBuilder Field Editions are created and configured for your study by StudyBuilder Professional or Enterprise Edition. Investigators and subjects who will collect study data can either enter data directly into the StudyBuilder Field Edition or onto automatically generated paper forms that can then be transcribed into Field Editions later.
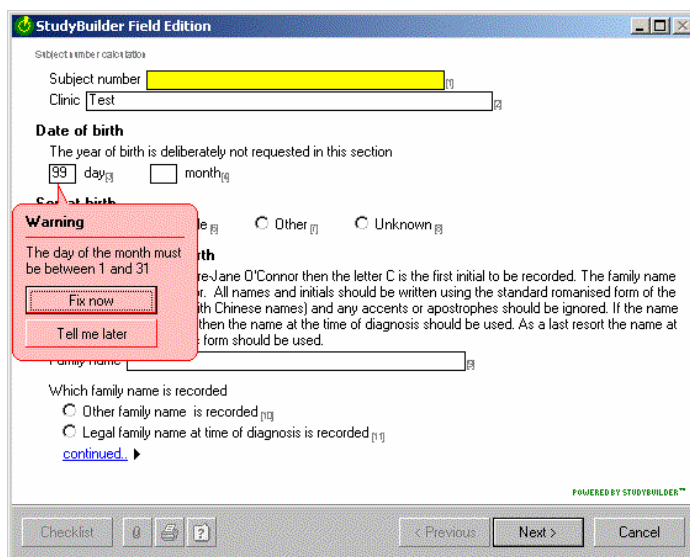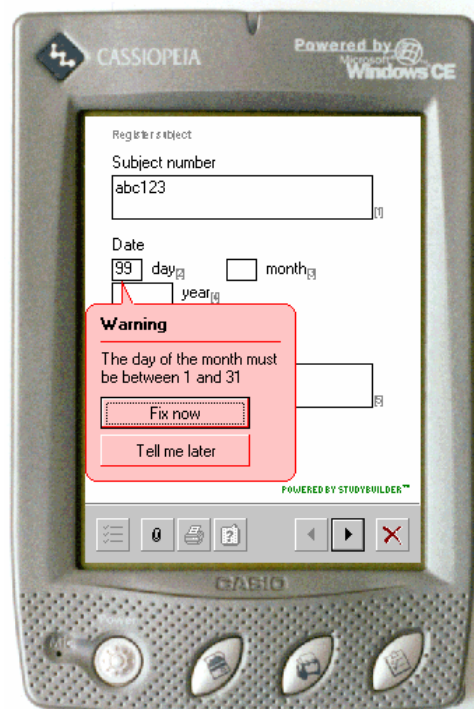
Simple to use, featuring the same wizard based interface as StudyBuilder Professional Edition, data is validated as it is entered allowing costly errors to be caught for instant correction. Secure data transport ensures that patient data gets to analysts and monitors quickly and conveniently by email, disk or network connection.

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[1] StudyBuilder Field Edition can be distributed to an unlimited number of sites in an unlimited number of studies if the study is designed with StudyBuilder Professional Edition, StudyBuilder Enterprise Edition or StudyBuilder Enterprise Server. Not all versions of StudyBuilder Field Edition are included with all StudyBuilder products - see later table.

Use StudyBuilder Field Edition to manage your study

- StudyBuilder Field Edition is a complete data and query management system
- Patient visit tracking system
- Adverse event tracking
- Patient recruiting database
- For standalone or network installations on multiple platforms
- Built in user and data transport security
- Build FDA 21 CRF Part 11 compliant systems
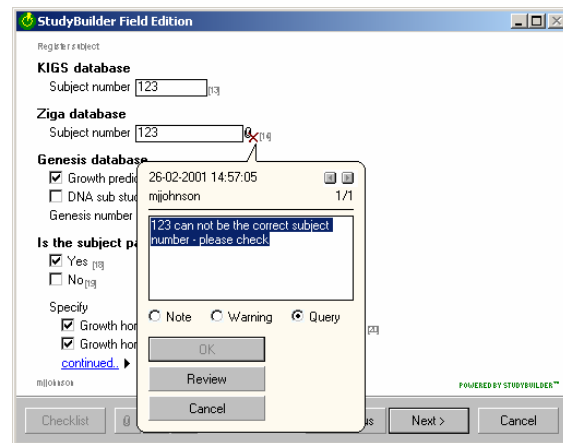
StudyBuilder Field Edition can dramatically reduce the time and money you invest in operating studies, audit, registries and clinical trials. With StudyBuilder Field Edition, the large amount of paperwork you now manage manually is managed automatically on a computer. All you have to do is enter data, queries, budgeting and other management information and StudyBuilder Field Edition can perform the calculating, organising, and reporting for you.

Configure StudyBuilder Field Edition as a patient recruiting module allowing you to:
- Search your database for patients who meet inclusion/exclusion criteria
- Store demographic information about patients and other contacts
- Track which advertising your patients respond to

Not only will StudyBuilder Field Edition improve your general study administration, it can help you enroll more appropriate patients in your studies, lowering the cost of your advertising and keeping your recruiting efforts organised.

Download data directly from devices into your data management system

Now you can automatically download data from devices used to make measurements in the clinic or at home.

Data can be downloaded by BlueTooth, infrared, serial, and USB connection on many platforms including the web! Supported devices include blood glucose meters. global positioning system (GPS) devices, spirometers and more. In addition you can capture barcode data from product packaging and specialized forms.

If we do not currently support a device you require, contact us and we will do our best to add support for you - free of charge!

StudyBuilder® — FIELD EDITION

Technical Information

This table shows which versions of StudyBuilder Field Edition are supplied with which StudyBuilder design tools along with sample system requirements. If you require support for an unlisted system please contact us and we will pleased to help.

Key:

S — Supplied as standard

V — Supplied as standard with appropriate version (e.g. Apple MacOS version is supplied with StudyBuilder Personal Edition for Apple MacOS)

O — Available as an option at additional cost. Contact StudyBuilder for details.

	StudyBuilder Student Edition	StudyBuilder Personal Edition	StudyBuilder Professional Edition	StudyBuilder Enterprise Edition	StudyBuilder Enterprise Server	StudyBuilder Developer Edition
Apple MacOS Power Macintosh required, System 7.1 or higher, 8MB RAM, 4MB storage	V	V	S	S	S	V
EPOC [2] e.g. Psion Series 5mx, Series 7, NetBook, Ericsson MC218 Revision 5, Java Virtual Machine, 100KB RAM, 100KB storage				S	S	V
Games consoles Nintendo Gameboy Advance, Microsoft XBox, Sega Dreamcast and Sony Playstation 2. Please contact us for details of availability by special order.				O	O	V
GEOS [2] e.g. Nokia Communicator 9000, 9110 64KB RAM, 64KB storage				S	S	V
Java [2]r Java applet compliant container or browser (JRE 1.1.2 or higher)				O	O	V
PalmOS [2] e.g. Palm III/V/VII/mx0x, Handspring Visor, IBM Workpad, Symbol Technologies series PalmOS 3.1 or higher, 64KB RAM				S	S	V
Linux OS e.g. Corel Linux 2.0 or higher, Red Hat Linux 7.0 or higher x86 processor, 16MB RAM, 16MB storage	V	V		S	S	V
Microsoft DOS 6.22 [2] 640 KB RAM, 720KB storage				O	O	V
Microsoft Windows/Windows for Workgroups 3.11 386 or higher processor, 4MB RAM, 4 MB storage				S	S	V
Microsoft Windows 95/98/2000/2003/ME/NT/Tablet/XP 4 MB RAM, 4MB storage	V	V	S	S	S	V
Microsoft Windows CE/Mobile/PocketPC e.g. HP iPaq/Journada, Casio E100 series, Symbol Technologies series and more Windows CE 2 or higher/Mobile/PocketPC, SH3/MIPS/ARM/XScale, 2 MB RAM, 2MB storage	V	V	S	S	S	V
Symbian OS				O	O	V
Unix See Linux OS for 'off the shelf' UNIX support. Please ask us about support for Solaris, AIX, etc.				O	O	V
Wap/iMode [2] WAP 1.0 compliant or iMode handset. Available by special arrangement				O	O	V
Web browser Requires Microsoft Internet Explorer 4.0 or higher, Netscape Communicator[2] 4.0 or higher. Other browsers may be compatible but may require validation.				S	S	V

[2] Support for platform is only provided for use in an online/wireless environment with data stored on a central server. This may be because we judge these platforms' native data storage and/or operating systems insufficiently reliable and/or standard to be suitable for long-term clinical data collection and archiving. If you wish to overrule this judgment we can accommodate you on a case-by-case basis at your own risk and for additional cost.

StudyBuilder Enterprise Server   **from $9,999 / €9,999 / £5,999 / ¥999,000**

StudyBuilder Enterprise Server is a pre-configured web server that allows up to fifty simultaneous study designers (subject to the purchase of sufficient designer licenses) to design studies via their web browsers. Designers can work on the same study, build custom question and study libraries, and use integrated data collection tools.

Based on StudyBuilder Enterprise Edition, StudyBuilder Enterprise Server brings the power and flexibility of collaborative study design to the web. Collaboration over the web makes it possible for local and internationally distributed study design teams to work together. Data can be collected on the same machine on which your studies are designed, deployed at MyStudyBuilder.com or installed on systems of your choice, either self standing or connected to systems such as Oracle and SQL Server.

StudyBuilder Enterprise Server is supplied preinstalled on a server running Microsoft Windows Server 2003[3] ready to be used out of the box or hosted in our data centre for up to one year at no extra charge. Packaged in a space saving 1U rack mount form factor, this powerful yet compact system allows a StudyBuilder Enterprise Server to be hosted in any data centre.

StudyBuilder Enterprise Server including one concurrent study designer license
Base server   EAN9781904694298 $9,999 / €9,999 / £5,999 / ¥999,000

Additional concurrent study designer licenses for StudyBuilder Enterprise Server
1 additional license   EAN9781904694304 $9,999 / €9,999 / £5,999 / ¥999,000
5 additional licenses   EAN9781904694311 $39,999/€39,999/£23,999/¥3,999,000

MyStudyBuilder.com™   **$4,999 / €4,999 / £2,999 / ¥499,000 per quarter[4]**

MyStudyBuilder.com is the one stop data hosting service for studies designed with StudyBuilder Professional Edition, StudyBuilder Enterprise Edition or StudyBuilder Enterprise Server. Select the 'Locate at MyStudyBuilder.com' option and your study will automatically have a private web site built and deployed on dedicated servers:

- YOUR OWN DEDICATED WEB SERVER WITH YOUR OWN DOMAIN NAME
- 24X7X365 SERVICE AND BACKUP SUPPLIED BY US
- A PRE-CONFIGURED DATABASE READY FOR LOADING WITH YOUR STUDY
- ONE CLICK STUDY DEPLOYMENT TO YOUR SERVER FROM WITHIN STUDYBUILDER TOOLS

You can also integrate data collected by StudyBuilder Field Edition running on palmtops and other devices at no extra charge.

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[3] A Red Hat Linux version is also available. Please contact StudyBuilder sales staff for more information.
[4] Assumes 30 forms per participant with 30 questions per form (5 GB database/100 GB data transfer per month)

Hardware products

StudyBuilder StudyPrinter
EAN9781904694411 $9,999 / €9,999 / £5,999 / ¥999,000

StudyBuilder StudyPrinter can print, staple and hole punch up to 37 full colour or monochrome, single or double sided forms, cover letters, patient information sheets or posters per minute directly from StudyBuilder software.

StudyBuilder StudyMailer
EAN9781904694427 $3,499 / €3,499 / £1,999 / ¥349,000

Once forms, cover letters and patient information sheets have been printed, StudyBuilder StudyMailer can insert them into up to 1,350 envelopes per hour ready for mailing to study subjects and sites.

StudyBuilder StudyWriter
EAN9781904694434 $3,499 / €3,499 / £1,999 / ¥349,000

StudyBuilder software can instruct StudyBuilder StudyWriter to transfer and label up to 50 customised copies of StudyBuilder Field Edition per hour to CD-ROM, DVD or memory card[5].

Academic software for pilot projects

StudyBuilder Personal Edition is only available for purchase by staff members of academic institutions. StudyBuilder Student Edition is only available for purchase by registered students of academic institutions. Proof of student status by supplying a copy of an International Student Identity Card is required for product activation.

These products have many of the features of StudyBuilder Professional Edition with the restriction that only a single copy of StudyBuilder Field Edition can be used to collect data on the type of computer specified by the particular version purchased. No upgrades are available and limited web only support is provided.
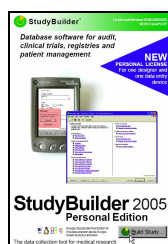
StudyBuilder Personal Edition $499 / €499 / £299 / ¥49,900
StudyBuilder Student Edition $149 / €149 / £99 / ¥14,900

Version	Personal Edition	Student Edition
Windows 95/98/2000/2003/ME/NT/XP	ISBN-1-904694-53-5W	ISBN-1-904694-54-3W
Windows CE/Mobile/Pocket PC	ISBN-1-904694-53-5C	ISBN-1-904694-54-3C
Mac OS	ISBN-1-904694-53-5M	ISBN-1-904694-54-3M
Linux OS	ISBN-1-904694-53-5L	ISBN-1-904694-54-3L

Please note that Microsoft Windows 95/98/2000/2003/ME/NT/TabletPC/XP is required to design studies irrespective of the version purchased.

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[5] Supports CompactFlash, MicroDrive, SmartMedia, Secure Digital, MultiMediaCard, Memory Stick and USB memory

To place an order or to learn more about StudyBuilder products contact your nearest office today

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ROBERT ROBINSON AVENUE
OXFORD OX4 4GP, UNITED KINGDOM
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TEL/FAX: +44 (1865) 338 092 / 100

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INTERNET
WEB: WWW.STUDYBUILDER.COM
E-MAIL: INFO@STUDYBUILDER.COM

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Accessories and support packages

StudyBuilder products are designed to provide everything you need for your study out of the box. However, we have a number of optional enhancement and support packages to make your study design and management even more convenient.
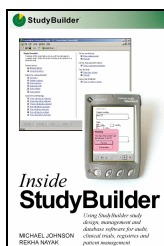
Inside StudyBuilder
ISBN-1-904694-50-0 $49.99 / €49.99 / £29.99 / ¥5,990

Inside this guide to a remarkable new method of performing medical research: key features; tutorial introduction; description of built-in wizards plus drag and drop tools; how to get the most out question libraries and designing your own; reusing question and study designs; data management; exercises; validation language and function reference; installation guides for desktops, servers and palmtops; data analysis; multimedia tutorial preview and more.

StudyBuilder Compatibility Pack for Apple Mac OS
ISBN-1-904694-21-7 $499 / €499 / £299 / ¥49,000

StudyBuilder Compatibility Pack for Linux OS
ISBN-1-904694-22-5 $499 / €499 / £299 / ¥49,000

StudyBuilder design tools including StudyBuilder Professional Edition and StudyBuilder Enterprise Edition are shipped as standard to run on Microsoft Windows operating systems. If you wish to run these tools on your Apple Mac OS or Linux OS computer these packs provide all the necessary software to do so. Note that if you want collect data using StudyBuilder Field Edition for Apple Mac OS or Linux OS devices you do not need these packs.
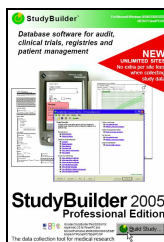
StudyBuilder One Year Support Renewal Pack

StudyBuilder Product	ISBN	Price
StudyBuilder Professional Edition	ISBN-1-904694-23-3	$499 / €499 / £299 / ¥49,000
StudyBuilder Enterprise Edition	ISBN-1-904694-24-1	$1,499 / €1,499 / £999 / ¥149,000
StudyBuilder Enterprise Server	EAN9781904694328	$2,999 /€2,999 /£1,999 /¥299,000/user
(with one year hosting)	EAN9781904694441	$4,999 /€4,999 /£2,999 /¥499,000/user

StudyBuilder products come with one year of upgrades and technical support. To extend this support for one or more years, purchase the appropriate support renewal pack before the support period expires.

StudyBuilder Upgrade Packs

StudyBuilder Upgrade Pack	ISBN	Price
Personal to Professional Edition	ISBN-1-904694-25-X	$999 / €999 / £699 / ¥99,000
Professional to Enterprise Edition	ISBN-1-904694-26-8	$3,499 / €3,499 / £1,999 / ¥349,000
Enterprise Edition to Enterprise Server	EAN9781904694335	$4,999 / €4,999 / £2,999 / ¥499,000

To upgrade more than one step, e.g. Personal Edition to Enterprise Edition you need to buy all the packs between steps, e.g. Professional Edition upgrade and Enterprise Edition upgrade.

StudyBuilder Training

Four training courses are available with certificates of attendance issued to attendees who successfully complete the onsite courses. Courses comprise lectures and hands on exercises with post course homework. Courses are available onsite given by a certified StudyBuilder trainer, on video, CD-ROM, DVD and online.
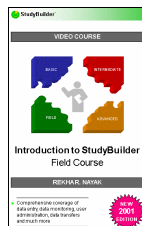
Introduction to StudyBuilder – Field Course

Onsite	SB-7-4-8-2	\$749 / €749 / £499 / ¥74,000/person[6]
CD ROM	ISBN-1-904694-05-5	\$149 / €149 / £99 / ¥14,000
DVD	ISBN-1-904694-34-9	\$149 / €149 / £99 / ¥14,000
Online	SB-7-4-8-2I	\$149 / €149 / £99 / ¥14,000
Video	ISBN-1-904694-04-7	\$149 / €149 / £99 / ¥14,000

The Introduction to StudyBuilder Field Course has been created for data entry staff, data managers and system administrators who will use StudyBuilder Field Edition to collect and manage data in the field. The course consists of a session aimed at data entry staff and a session aimed at data managers and administrators. Both sessions contain lectures and hands on exercises and take approximately half a day to complete.

Introduction to StudyBuilder – Basic Course

Onsite	SB-7-4-8-3	\$749 / €749 / £499 / ¥74,000/person[6]
CD ROM	ISBN-1-904694-07-1	\$149 / €149 / £99 / ¥14,000
DVD	ISBN-1-904694-35-7	\$149 / €149 / £99 / ¥14,000
Online	SB-7-4-8-3I	\$149 / €149 / £99 / ¥14,000
Video	ISBN-1-904694-06-3	\$149 / €149 / £99 / ¥14,000

This course aimed at new users of StudyBuilder Professional Edition or StudyBuilder Enterprise Edition explains the principles behind StudyBuilder design tools and how to use them to design studies in practice. Consisting of a morning study design session and an afternoon data entry and data management session, this course gives attendees a though grounding in the use of StudyBuilder tools. Both sessions contain lectures and hands on exercises and the course takes one day to complete.

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[6] Minimum of four people per training session, maximum of 10. Assumes client supplies training site. Surcharge of \$750/€750/£500/¥75,000 per day applies if StudyBuilder is to supply training site. Includes all course materials including documentation, CD ROMs and student laptop and palmtop computers for exercises.

Introduction to StudyBuilder – Intermediate Course

Onsite	SB-7-4-8-4	$2,999 /€2,999 /£1,999 /¥299,000/person[7]
CD ROM	ISBN-1-904694-09-8	$299 / €299 / £199 / ¥29,000
DVD	ISBN-1-904694-36-5	$299 / €299 / £199 / ¥29,000
Online	SB-7-4-8-4I	$299 / €299 / £199 / ¥29,000
Video	ISBN-1-904694-08-X	$299 / €299 / £199 / ¥29,000

The Introduction to StudyBuilder Intermediate Course is an in depth guide to study, question and validation design for study designers. Sessions contain lectures and hands on exercises and the course takes one and a half days to complete.

Introduction to StudyBuilder – Advanced Course

Onsite	SB-7-4-8-6	$2,999 /€2,999 /£1,999 /¥299,000/person[7]
CD ROM	ISBN-1-904694-38-1	$299 / €299 / £199 / ¥29,000
DVD	ISBN-1-904694-39-X	$299 / €299 / £199 / ¥29,000
Online	SB-7-4-8-6I	$299 / €299 / £199 / ¥29,000
Video	ISBN-1-904694-37-3	$299 / €299 / £199 / ¥29,000

The StudyBuilder Advanced Course is designed for system administrators and study designers intending to design and implement multicentre trials. The course describes how to scale and configure peer-to-peer and hierarchical transfers of data, deployment on Windows, Macintosh, Linux, Web and palmtop platforms. The course takes one and a half days.
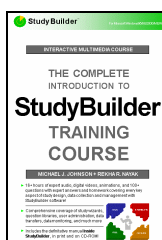
The Complete Introduction to StudyBuilder Training Course

Onsite	SB-7-4-8-7	$4,999 /€4,999 /£2,999 /¥499,000/person[7]
CD ROM	ISBN-1-904694-11-X	$499 / €499 / £299 / ¥49,000
DVD	ISBN-1-904694-40-3	$499 / €499 / £299 / ¥49,000
Online	SB-7-4-8-5I	$499 / €499 / £299 / ¥49,000
Video	ISBN-1-904694-10-1	$499 / €499 / £299 / ¥49,000

The Complete Introduction to StudyBuilder Training Course includes the Field, Basic, Intermediate and Advanced training courses as well as the definitive reference 'Inside StudyBuilder'.

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[7] Minimum of two people per training session, maximum of 5. Assumes client supplies training site. Surcharge of $750/€750/£500/¥75,000 per day applies if StudyBuilder is to supply training site. Includes all course materials including documentation, CD ROMs and student laptop and palmtop computers for exercises.
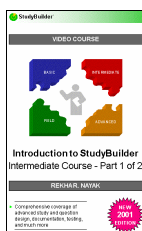
StudyBuilder Design Consultancy

$299 / €299 / £199 / ¥29,900 per hour off site
$599 / €599 / £399 / ¥59,900 per hour on site

If you wish to outsource study design and implementation based on StudyBuilder products then our consultants will be pleased to help you. The hours required depend on the complexity of your study, but typically if you have a protocol and paper case report form you should budget approximately four hours of consultancy per case report form page (includes layout, development of validation criteria, documentation and testing) typically resulting in a total of between 40 and 160 hours being required per study.

StudyBuilder On-Call

$4,999 / €4,999 / £2,999 / ¥499,000 per 5 incidents

StudyBuilder On-Call gives you guaranteed response time telephone and email based technical support for study design problems or problems at study sites. An incident consists of up to four hours of technical support to resolve your problem with additional hours charged at the standard StudyBuilder Design Consultancy rate.

StudyBuilder On-Call On-Site

$9,999 / €9,999 / £5,999 / ¥999,000 per 5 incidents

StudyBuilder On-Call On-Site gives you guaranteed response time on-site technical support for study design problems or problems at study sites. An incident consists of up to four hours of on-site technical support to resolve your problem with additional hours being charged at twice the standard StudyBuilder Design Consultancy rate.

StudyBuilder Source Escrow

$9,999 / €9,999 / £5,999 / ¥999,000 per annum

This new service aims to provide customers using StudyBuilder products in mission critical applications with the peace of mind that comes from knowing that they have access to the source code of the particular versions of StudyBuilder software deployed in a study if the worst happens. The new service is offered on an annual subscription basis per product and version of the product for which the escrow service is required. Our third party escrow agent only releases the source code if we withdraw a product and support for it is officially ceased or if we cease trading. Use of source code is limited to maintenance and support activities.

StudyBuilder Accelerated Development

Price On Application

StudyBuilder is constantly working to ensure that our products include the features you need. If you need a particular feature we have not implemented yet, please contact us to see if we can accelerate development for you.

StudyBuilder®

StudyBuilder software and services are used by individuals, local, national and international organisations in more than 40 countries by tens of thousands of users to design studies and collect data for academic and industrial research. Below are some of our clients:

Pharmaceutical and Cosmetics
=====================================
Amgen
AstraZeneca
Elan Pharmaceuticals
Gautier Laboratory
Grünenthal
IDEC Pharmaceuticals
Janssen-Cilag
Napp Pharmaceuticals
Neuromedicin
Procter and Gamble
Serono Pharmaceuticals
The Liposome Company

Medical Devices
=====================================
Baxter Healthcare
Blue Medical Devices
Control Delivery Systems
Entremed
Gambro
Guidant
Medtronic
Rhinometrics
Stryker
Thermocore Medical Systems
Transneuronix

Contract Research Organisations
=====================================
IHC
Marlar International
Metadata Solutions
Painancea
Parexel International
Quintiles Transnational

Integrators
=====================================
Bohn Stafleu Van Loghum
Cyenc
Euro RSCG Interactive
IBM
Integrated Medical Systems

Government, Non-Governmental Organisations and Military
=====================================
Australian Society of Dental Anesthesiology
National Institutes of Health
National Health Service
Naval Hospital Vina Delmar
United States Department of Defense
Wellcome Trust
World Health Organisation

Hospitals and Site Management Organisations
=====================================
Alberta Children's Hospital
Amsterdam Medical School
Atlantic Eye and Face Centre
Charles University Hospital
Evgenidon Hospital Athens
Fresenius Medical Care
Ijsland Ziekenhuis
Kantonshopital Basel
Karolinska Hospital
Mount Sinai Hospital
P. Stradins University Hospital
Rikshospitalet
Royal Brompton Hospital
St. Bartholomews Hospital
Tati River Clinic
Warsaw Central Hospital

Universities
=====================================
Cairo University
Erasmus University Medical School
Johns Hopkins University School of Medicine
McGill University
McMaster University
University of Gent
University of Leiden
University of London
University of Michigan
University of Oxford
University of Palermo
University of Washington
Wits University

StudyBuilder supplies customers around the world including: Argentina, Australia, Austria, Belgium, Botswana, Canada, China, Colombia, Czech Republic, Chile, Denmark, Egypt, Estonia, France, Germany, Greece, India, Israel, Italy, Japan, Kenya, Latvia, Mexico, Norway, Poland, Saudi Arabia, South Africa, Sweden, Switzerland, Thailand, The Netherlands, The Philippines, Turkey, United Kingdom, United States of America, Venezuela and more so you can be confident that we will supply your needs wherever you are.

To place an order or to learn more about StudyBuilder products contact your nearest office today

StudyBuilder ®

Immediate Benefits for Study Designers

- SAVE MONEY

- SAVE TIME – DESIGN AND DEPLOY STUDIES IN DAYS NOT MONTHS

- INTERACT WITH THE ACTUAL MATERIALS TO BE USED IN THE FIELD

- VALIDATED TRANSLATIONS OF STUDY QUESTIONS INTO OTHER LANGUAGES
  - FACILITATES PARTICIPATION OF STUDY CENTRES SPEAKING DIFFERENT LANGUAGES
  - ENSURES THAT ALL STUDY SUBJECTS WHO ARE NOT NATIVE SPEAKERS OF THE LANGUAGE OF STUDY DESIGNER OR CENTRE CAN PARTICIPATE FULLY

- RETURN COMPLETE CONTROL OF STUDY DESIGN TO STUDY DESIGN PROFESSIONALS
  - CONCENTRATE ON HIGH QUALITY CONSISTENT STUDY DESIGN WITHOUT WORRYING ABOUT THE SPECIFICS OF IMPLEMENTATION
  - PAPER FORMS, COMPUTER DATA COLLECTION AND MANAGEMENT AND OTHER TOOLS ARE AUTOMATICALLY CREATED, CONFIGURED AND PACKAGED FOR DISTRIBUTION

- INCREASE DATA QUALITY
  - AUTOMATIC VALIDATION ON ENTRY
  - SYSTEMATIC DATA COLLECTION TOOLS BASED ON VALIDATED DESIGNS

- COLLECT DATA ON VIRTUALLY ANY DESKTOP OR HAND HELD COMPUTER

- EXTENSIVE LIBRARY OF VALIDATED STUDY QUESTIONS
  - LITERATURE SCANNING TEAM ENSURES THAT LIBRARIES ALWAYS UP TO DATE
  - IMPROVED QUESTION LIBRARIES AND SOFTWARE CAN BE DOWNLOADED AT ANY TIME

- MAKE PRODUCING AND DEPLOYING HIGH QUALITY STUDIES ON TIME AND UNDER BUDGET THE NORM, RATHER THAN THE EXCEPTION

StudyBuilder Professional Edition and StudyBuilder Enterprise Edition allow doctors and clinical scientists to design and deploy a clinical study or trial in days rather than months, dramatically reducing the amount of effort and investment required to perform a study. However, as study design is a process of continuous refinement the benefits do not stop there. Once a study has been designed it can be continuously refined and reused, saving time and money on not just one, but all your studies.

By dragging and dropping questions from our extensive study libraries onto interactive 'what-you-see-is-what-you-get' representations of the actual materials that will be used in the field, you get to experience first hand what will happen during data collection. The study materials can include paper forms, electronic databases (remote data entry systems) and associated documentation.

Multilingual project management

StudyBuilder products also eliminate the language bottleneck, facilitating cooperation with centres participating in national or multinational studies. These days more and more trials require studies of multinational populations with study participants being fortunate if the study materials are available in their native language. The cost and difficulty of obtaining high quality translations often means that data collection occurs in the investigator or subject's second or third language, with all the opportunities for errors that implies – unless you use StudyBuilder!

The study designer specifies in which countries the study will take place and the software automatically includes translations of study materials into the appropriate languages. The translations are not machine translations – highly qualified translation personnel have made all the translations. StudyBuilder uses these translations to automatically repackage study materials into the appropriate language. You can also modify or add your own translations if you require.

The software takes the user step by step through the production of complete packs of materials to be sent to specific centres participating in the study. StudyBuilder products are designed to be affordable and applicable for studies ranging in size from tens to tens of thousands. At the moment the program can produce study materials in Chinese, Dutch, English, French, German, Italian, Japanese, Spanish and Modern Standard Arabic, with others available on request.

Complete control back to study design professionals

StudyBuilder returns complete control of study design to study design professionals. At the moment study design methodologies are largely informal with many opportunities for miscommunication and errors. The lack of formal specifications often leads to sub standard systems. Returning control of the study design to the study design professionals, our products ensure that high quality consistent study design can be concentrated upon without the worry of implementation specifics. With StudyBuilder, paper forms, computer data collection and management tools are automatically created, configured and packaged for distribution. The study designer can see changes in their design immediately and automatically. Effects of design changes can be seen in the study specifications, manuals and protocols immediately.

Certificates of Study Authorship

All StudyBuilder products sign your studies with your unique Certificate of Study Authorship (CoSA) allocated when you buy a StudyBuilder product. The CoSA is used as a digital signature so that users can be sure that you designed your study and to assist you protect your intellectual property.

StudyBuilder®

Extensive library of validated questions

StudyBuilder programs use our extensive library of validated study questions. We continuously monitor the scientific literature to ensure that its question libraries are current and relevant. A rigorous peer review process ensures that the questions are of the highest quality. These questions are then translated and further validated by specialist personnel.

Improved question libraries and software can be downloaded at any time from the StudyBuilder web site (http://www.studybuilder.com or see the section 'Contacts' for your nearest site) or from update CD ROMs that registered users can opt to receive after the purchase of a qualifying product.

If you need to add your own questions to the question libraries, simply use the built in question design tools. Alternatively, contact the StudyBuilder Study Implementation Service who can implement your existing forms or CRFs free of charge if we can use any questions we do not already have in our question libraries in future StudyBuilder products.

Internationally standardized rating scales and questionnaires

Should you require an internationally accepted rating scale or questionnaire not yet included in our library of validated study questions, please notify our development department. Upon notification, we guarantee to include such rating scales and questionnaires in our libraries within 28 days, provided there are no copyright issues.

Collect data on virtually any computer

StudyBuilder study design tools (StudyBuilder Professional Edition, StudyBuilder Enterprise Edition, StudyBuilder Personal Edition and StudyBuilder Student Edition) run on Microsoft Windows 95/98/2000/2003/ME/NT/Tablet/XP. The data collection and management system (StudyBuilder Field Edition) runs on most computers including personal digital assistants, smart mobile telephones, as well as traditional desktops and servers allowing the designer to select the correct tool for each part of the study and to adapt to local means of working.

To place an order or to learn more about StudyBuilder products contact your nearest office today

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Internet and CD ROM updates

In the twelve months following your purchase of StudyBuilder Professional Edition or StudyBuilder Enterprise Edition you can update your software and question libraries via the Internet. Thanks to StudyBuilder's commitment to continuous product development, these updates will contain additional languages, data collection platforms and features as soon as we add them and at no extra cost. If you wish to continue this service after the initial twelve months you may purchase annual support pack before this period expires. The support pack includes the latest CD-ROM and manual.

Your study investigators are not left out. Updates to the various StudyBuilder Field Editions be can downloaded from a web site as part of the core product update – no payment or maintenance agreement by the investigators is necessary. In addition, if a new platform is added to the already comprehensive list of support platforms, or an investigator wishes to change from one platform to another – no problem! Just go to the StudyBuilder web site, download the appropriate StudyBuilder software update and run the transfer wizard to bring all the existing studies into the new version of the software.

StudyBuilder Knowledge Base

Puzzled by some feature of the software or doing a particularly tricky bit of system integration? No problem – just visit the StudyBuilder Knowledge Base at your nearest StudyBuilder web site. An online support system with hints, tips, fixes and frequently asked questions to get you on the right track as soon as possible, free and unlimited for as long as you own a qualifying StudyBuilder product.

StudyBuilder Support Services

For trickier problems, contact StudyBuilder Support Services by email and address your question directly to a technical support specialist.

StudyBuilder® — FREQUENTLY ASKED QUESTIONS

Which product should I buy?

Key:
○ Optional feature
● Standard feature

Feature	Student Edition	Personal Edition	Professional Edition	Enterprise Edition	Enterprise Server
Study design features					
Study design wizards	●	●	●	●	●
Drag and drop question selection	●	●	●	●	●
Design your own questions	●	●	●	●	●
Distribute your own questions to other users for new study designs				●	●
Install design software on your own computer for your own use	●	●	●	●	
Design software preinstalled on a server for many people to use					●
Multi-user study design and review features				●	●
Advanced multicentre study design and management features				●	●
Paper documentation (electronic supplied with all products)	○	○	●	●	●
Complete Introduction to StudyBuilder Training Course (Online)	○	○	○	○	●
Data collection and data management features					
Use StudyBuilder Field Edition on your own computer	●	●	●	●	●
Distribute StudyBuilder Field Edition to unlimited sites and users			●	●	●
Includes StudyBuilder Field Edition for:					
Apple MacOS	○	○	●	●	●
EPOC (Psion)				●	●
Game consoles[8]				○	○
GEOS (Nokia Communicator)				●	●
Linux OS	○	○		●	●
Microsoft DOS				○	○
Microsoft Windows 3.x/Windows for Workgroups 3.xx				●	●
Microsoft Windows CE/Mobile/PocketPC	○	○	●	●	●
Microsoft Windows 95/98/2000/2003/ME/NT/XP	○	○	●	●	●
PalmOS				●	●
Programmers (ActiveX controls, DLLs and static libraries)				●	●
WAP/iMode[8]				○	○
Web browsers (via web server provided by you)				●	●
Web browsers (one click via web server supplied with product)					●
Store data use standard supplied StudyBuilder database	●	●	●	●	●
Store data using third party ODBC compliant database				●	●
Transfer data between users by floppy disk, LAN and email	●	●	●	●	●
Transfer data between users by internet				●	●

[8] May require additional license. Please contact StudyBuilder for details.

How does StudyBuilder study design software work?

StudyBuilder automates the study design process. This means that the design and management of studies is much quicker and easier than traditional methodologies. One of the keys to this ease of use is the study design wizard that systematically takes you through the process of building a study.

When it is time to choose what questions specific to your study you want to ask (the study design wizard having created a basic framework for your study) you enter the study desktop. On the left side of your screen you see an extensive library of ready made questions. You only have to select a question from the library and drag it to the right hand side of your screen (which contains what-you-see-is-what-you-get representations of your study materials) to add it to your study. Some questions have sub questions associated with them. For example, a generic date question will have 'day', 'month', and 'year' sub questions. If a question has sub questions they will automatically be added to the study at the same time as the main question.

If you want to see how your study will be used in the field, you can review the data collection preview on the right hand side of the screen to see interactive previews of the paper or electronic data collection forms - what-you-see-is-what-you-get.

Question order can be changed at any time. If you think a question at the beginning of the study would be more appropriate asked later, just pick it up with your mouse and drag it to the end of the study. All the documentation describing the study automatically updates to reflect this!

How do StudyBuilder question libraries work?

We continuously monitor the scientific literature to ensure that StudyBuilder's question libraries are current and relevant. A peer reviewed testing process ensures that the questions are of the highest quality. Updates can be downloaded from your nearest StudyBuilder web site.

What can you actually do with StudyBuilder products?

With StudyBuilder software you can easily design and manage audits, clinical trials, diaries, patient management systems and registries in just a few hours. And because study design is often a process of continuous refinement, you can update studies in the field rapidly and with no loss of data as frequently as you require – saving huge quantities of time and money.

Furthermore, the program facilitates cooperation with other centers participating in a study, especially international participants. You only have to specify which languages are required for data collection and the system will include translations - currently Chinese, Dutch, English, French, German, Italian, Japanese, Modern Standard Arabic and Spanish and are available in other languages on request.

To place an order or to learn more about StudyBuilder products contact your nearest office today

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StudyBuilder products return control of the study design process to study design professionals. At the moment traditional study design methodologies are largely informal with many opportunities for miscommunication and errors. With our software the control of the study is put back in the hands of the professionals. This ensures that you can concentrate on high quality and consistent study design with the software worrying about the specifics of implementation. With StudyBuilder, paper forms, electronic data capture and management tools and documentation are automatically created, configured and packaged for distribution.

With StudyBuilder products, the designer of the study can see changes in their design immediately and automatically. Authorship and revision histories are tracked allowing systematic auditing and control of the study design process. Studies and study data can be digitally signed to prove authorship and ensure security.

What types of study can I build?

Any! We have libraries for a huge range of diseases and specialties. Questions for a huge range specialties and diseases are included. You can collect data for audits, clinical trials, diaries, patient management systems, registries and more - in fact any kind of systematic medical data collection you can think of.

Audit

Design:
Study designed by audit coordinator using StudyBuilder Professional Edition

Data collection:
Paper and electronic forms completed in StudyBuilder Field Edition on PCs and palmtops by staff

Data entry and management:
Data transcribed from paper forms and electronic data reviewed for errors in StudyBuilder Field Edition by staff

Analysis/reporting:
Results view in electronic or paper output from StudyBuilder Field Edition or third party analysis tool

Registries

Design:
Study designed using StudyBuilder Professional or Enterprise Edition by registry headquarters

Data collection:
Paper/electronic forms sent to clinics (or downloaded from web site) for completion by investigators. Collected data sent to registry headquarters

Data entry and management:
Data transcribed from paper forms and electronic data reviewed for errors in StudyBuilder Field Edition by registry headquarters

Analysis/reporting:
Results sent as paper or electronic output to participating clinics

Patient management system

Design:
Study designed using StudyBuilder Professional Edition by care team

Data collection:
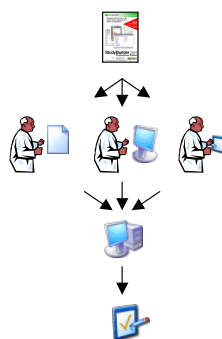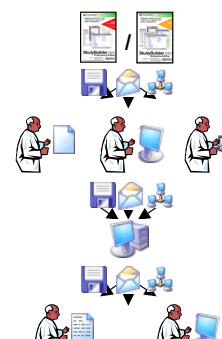Paper and electronic forms completed in StudyBuilder Field Edition on PCs and palmtops by staff

Data entry and management:
Data transcribed from paper forms and electronic data reviewed for errors in StudyBuilder Field Edition by staff

Analysis/reporting:
Histories and reports viewed using StudyBuilder Field Edition or as paper output
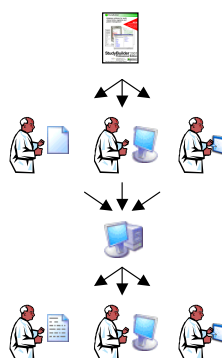
Clinical trials and patient diaries

Design:
Study designed using StudyBuilder Enterprise Edition by study designer

Data management:
Data collection and management materials distributed to local study coordinators. Data received and reviewed electronically with queries and reports raised and reviewed as necessary

Data collection:
Paper and electronic forms sent to sites or viewed/downloaded on web site and completed by investigators and/or subjects (e.g. patient diaries). Electronic data is instantly available centrally for monitoring and analysis

What type of computer does it run on?

StudyBuilder Student Edition, StudyBuilder Personal Edition, StudyBuilder Professional Edition and StudyBuilder Enterprise Edition run on Microsoft Windows 95/98/2000/2003/ME/NT/Tablet/XP and can run on Apple MacOS and Linux OS with the additional purchase of one of our compatibility packs.

StudyBuilder Field Edition runs on a huge range of computers including desktops, palmtops, smart mobile phones and games consoles. Please contact StudyBuilder for the latest list of supported platforms.

Do the libraries include rating scales and questionnaires for my specialty?

Our scientific development team is continuously expanding the question libraries. Should you use an internationally accepted questionnaire or rating scale that is not yet included in the library, just notify our development department. We aim to include this questionnaire or rating scale in the standard library within 28 days, provided there are no copyright issues.

Can I incorporate my own questions and logic into studies?

Absolutely! One of the most powerful features of StudyBuilder products is the complete flexibility of study design, data flow, question validation criteria and so on.

Is there a limit to the number of questions that can be asked in a study?

The theoretical technical limit to the number of questions that can be asked is in the millions of questions per study. Of course this will never practically be used - most studies tend to have a few hundred questions in total.

What languages are StudyBuilder products programmed in?

C and C++. StudyBuilder products have been integrated with systems programmed in a wide range of languages including assembler, C, C++, Delphi, Pascal, Java, JavaScript, PowerBasic and Visual Basic running on processors including 68000, ARM/Xscale, MIPS, PowerPC, SH3 and x86. Please contact us if you require more details.

What database does it use?

We use our own integrated custom database. With StudyBuilder Enterprise Edition and StudyBuilder Enterprise Server you can also configure the system to use ODBC compliant databases such as DB2, Oracle, MySQL and SQL Sever if you prefer.

What audit trails and data security features are built into StudyBuilder software?

StudyBuilder software is designed and built to satisfy and exceed the technical requirements of regulatory requirements for electronic data collection specified by bodies such as the EU, FDA, and ICH.

StudyBuilder Field Edition, our data collection and management software, can either use its own built in database or third party databases such as SQL Server, Oracle and DB2. StudyBuilder software maintains a full audit trail for all data that is entered, modified or deleted irrespective of the native capabilities of the database that is used. In fact, StudyBuilder Field Edition never actually modifies or deletes data records – additional records are added to indicate that previously entered data needs to be revised or ignored. However, the original data is still recorded in the database and is fully accessible for analysis and review.

Whenever data is entered, the user name of the person entering the data, the date and time, the site, the type of device, the version of the software and more is recorded along with each piece of data that is recorded. Each record is digitally signed to ensure the integrity of individual records and to allow the detection of tampering of individual records. Groups of records are protected by checkpoints that allow the detection of attempts to insert or delete records into the database. In addition there are functions to detect attempts to modify the system date and time and fraudulent manipulation of the system.

When using the software, access is protected by usernames, passwords and site codes. If required, biometric identifiers such iris scanners and fingerprint readers can be used. Roles can be assigned to users, for example a data entry person might only be allowed to enter new data and not review and revise previously entered data.

How do I query data collected with StudyBuilder products?

StudyBuilder products are designed to enhance and improve the quality of data collected during the data collection process so that an analyst has a high quality clean data set to start work with. StudyBuilder products can export data all popular analysis packages including SAS, SPSS, Statistica and Microsoft Excel.

Can I use StudyBuilder software to create a third party database (e.g. Microsoft Access, Oracle, DB2, etc.) and then use the third party database or third party software as the query and reporting tool?

Yes - you can either tell StudyBuilder software to export data to the third party database or specify it as the native database engine.

When formulating questions, can you specify types such as date, number and list, and can you easily update selection lists after the creation of the study?

Yes - questions range from as simple as a checkbox or list through to something as complicated as a visual analogue scale or graph.

Can you specify validation rules for questions

Validation rules can be applied to the values of any question, between questions, on historical data, etc.

Can you create questions that accept multiple answers with no defined limit?

Yes, for example if you had a question asking for secondary diagnosis of some disease the study could be configured to allow you to supply as many secondary diagnosis as you can identify.

What documentation do StudyBuilder design tools produce?

From a technical point of view the software can generate database schemas and validation criteria specifications. From the study documentation point of view, the system can generate protocols and end user manuals.

Is there a reporting tool that comes with the product?

StudyBuilder software includes basic reporting forms within the product for data management purposes but is not designed to be a reporting tool. However, many distributions of the software include evaluation or free versions of popular reporting tools such as Crystal Reports and Seagate Info for your convenience.

How many computers can I install my software on?

For study design, StudyBuilder Student Edition, StudyBuilder Personal Edition, StudyBuilder Professional Edition, StudyBuilder Enterprise Edition and StudyBuilder Enterprise Server are licensed for installation on a single computer.

For data collection and management, StudyBuilder Field Edition (which is supplied with all StudyBuilder study design products) can be installed on a single computer by users of StudyBuilder Student Edition and StudyBuilder Personal Edition, and on an unlimited number of computers by users of StudyBuilder Professional Edition, StudyBuilder Enterprise Edition and StudyBuilder Enterprise.

For example, if a single institution is designing a multicentre trial, the institution can purchase a single copy of a study design product such as StudyBuilder Professional Edition or StudyBuilder Enterprise Edition and distribute StudyBuilder Field Edition to collect and manage data to all the participating centres at no additional cost.

If more than one centre wishes to design studies, then each centre that wishes to design studies needs to purchase StudyBuilder study design software.

How do I order it?

We accept orders on StudyBuilder standard order forms. If you give us your name, full postal address including your country or your fax number or email address we can send you one today.

What form of payment do you take?

Payment can be made by bank transfer, cheque or most major credit cards in most major currencies. Contact us for further information.

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FAMILY NAME

_____ (2)
GIVEN NAME

_____ (3)
HONORIFIC (E.G. MR, MRS, MS, DR, PROFESSOR)

_____ (4)
PROFESSION/SPECIALITY

CONTACT DETAILS

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EMAIL ADDRESS

_____ (6)
TELEPHONE

_____ (7)
FAX

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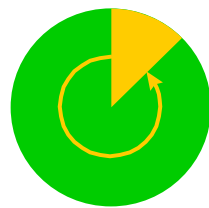TEL/FAX: +44 (1865) 338 092 / 100

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4 MyStudy: A StudyBuilder Tutorial

In this chapter, you will get a quick introduction to using StudyBuilder Professional Edition (this tutorial is also applicable to StudyBuilder Enterprise Edition users). The aim is to introduce you to the study wizard and show you some of the settings associated with a typical project.

The tutorial will demonstrate designing a basic registry for newborns to keep track of their growth. It is assumed that data will be collected at multiple centres in several countries on paper, Microsoft Windows 95 and Microsoft Windows CE devices.

The tutorial is divided into sections that match the major topics in the study wizard along with a brief introduction to using the system produced.

Creating a new study

This first section of the tutorial provides step-by-step instructions for creating a new StudyBuilder study. The aim of the section is to familiarise you with common StudyBuilder commands, windows and settings that you will use when creating and working with a study.

Start StudyBuilder Professional Edition

Find the icon for StudyBuilder Professional Edition on your system and start the program. This will typically be in your 'Start' menu, on your desktop or in the folder where you installed the software. While the program starts you will see a progress bar showing the study libraries loading. This can take a few minutes on slower systems.

Figure 1   The startup screen
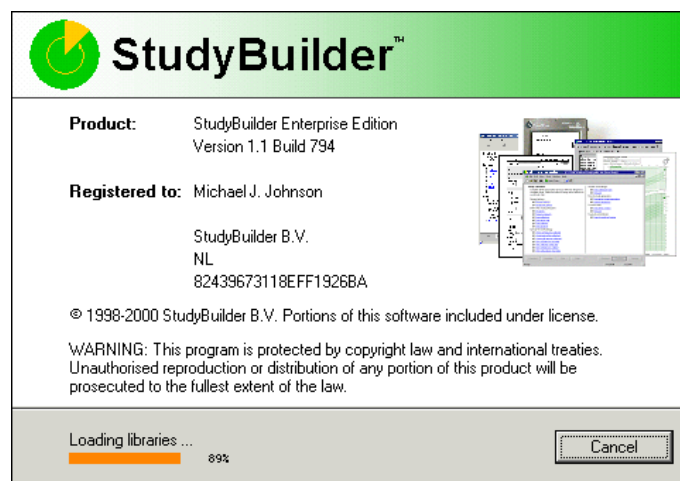
When the program has finished loading you will see a menu bar and toolbar appear as shown in Figure 2.

Figure 2 The menu bar
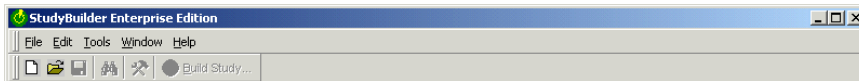
Create a new study

From the menu bar, select **File > New > Study…**. The program displays the **New Study** window (Figure 3). This window allows you to select a file name for your new study and a location on your hard drive or network to store it.

Figure 3 The New Study window
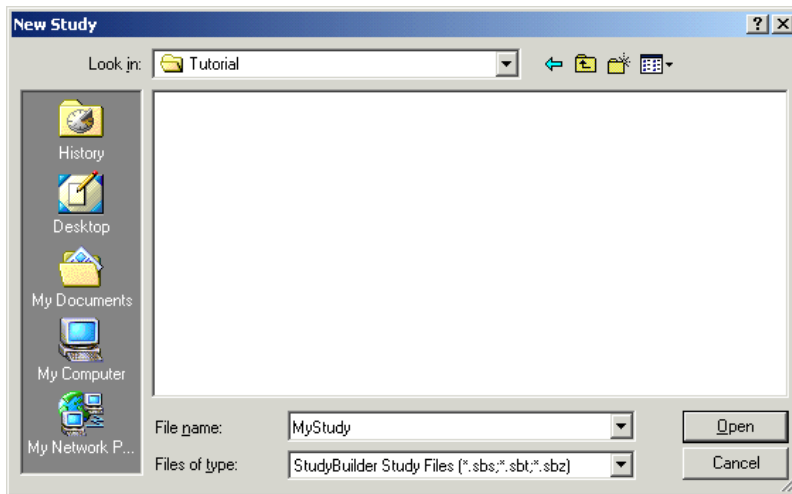
Make sure that you are in a directory where you wish to save the study. Enter a file name for the study, then click **Open**. The program will then create a study wizard window for your study.

Figure 4   The Study Wizard
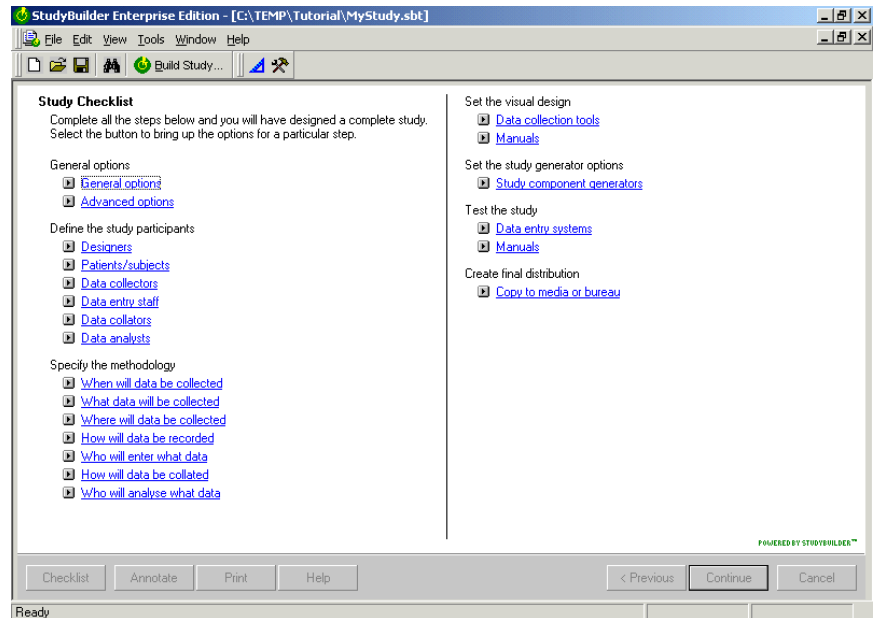
You are now ready to start designing your study.

General options

The General options section

With the study wizard open at the Study Checklist screen, click on the first button or hyperlink in the **General options** section of the checklist. You will see the **General options** page of the study wizard (Figure 5).

Figure 5   The General Options section

Type in a name for the study (for this example, use 'Growth registry') in the first question on the page. The program suggests that you use the default menu structure and you should not change this option. The study design is still in progress, so the 'Is the study design still in progress' section should be set to 'Yes'.
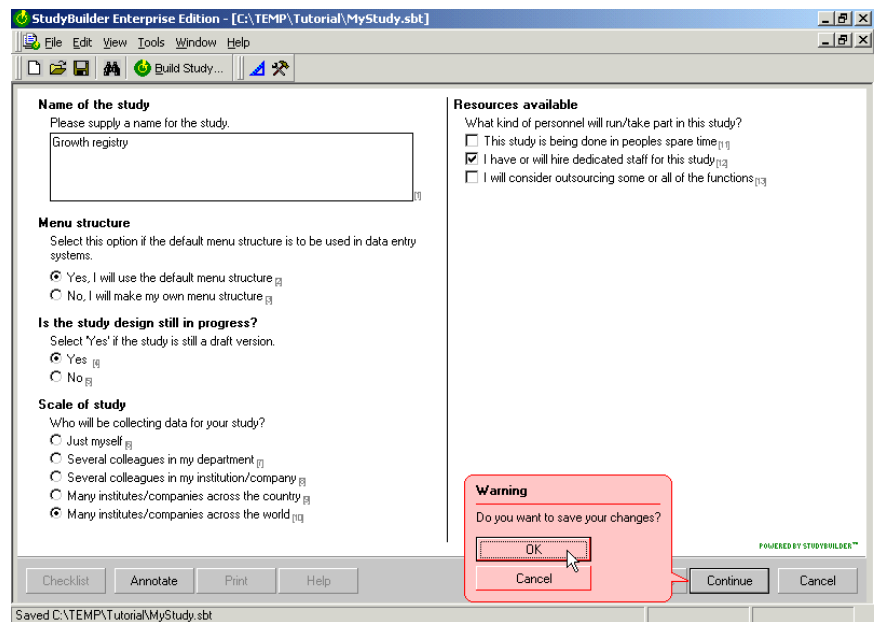
The scale of the study determines whether there are multiple centres in the study. In the case of this example there are multiple centres in multiple countries so the appropriate option should be selected. We will assume that dedicated staff are available for this study and select the appropriate option in the 'Resources available' section.

Once the appropriate selections have been made, click on the **Continue** button. A message asking you to confirm that you wish to save your changes will appear. You should click **OK** and you will be returned to the study checklist of the study wizard.

The Advanced options section

Next click on the **Advanced options** section in the study checklist. You will then see a screen requesting what type of study you wish to design. Select the **Patient registry** option. Click on the **Continue** button and confirm that you wish to save the changes by clicking **OK**.

You have successfully configured the general options of the study.

Participants

The next step of the design process is to specify the participants in the study, from designers through to subjects. With the study wizard open at the Study Checklist screen, click on the first button or hyperlink in the **Define the study participants** section of the checklist. You will see the **Designers** section of the study wizard

The Designers section

If you are using StudyBuilder Professional Edition you are not able to register individual study designers as it is a single user product and your information is stored within your certificate of study authorship. If you are using StudyBuilder Enterprise Edition you will see a screen allowing you to register individual designs and password protect your study design. We will not use this feature for this tutorial so users of both products should select the **Cancel** button and return to the main study checklist.

The Patients/Subjects section

Click on the **Patients/Subjects** button or hyperlink in the study checklist to go to the Patients/Subjects section.

Figure 6   The Patients/Subjects section

The **Type of primary subject** is **Human** so the appropriate option should be selected. This is a universal registry being performed by individuals who wish it to succeed so **Estimated degree of protocol compliance** should be **Fair**. We are proposing to use Microsoft Windows computers for data collection so we will estimate **Technological literacy** as **Fair**. The study is designed to track patients throughout the time that they are growing so the **Age categories** will include **Infant**, **Child** and **Adolescent**.

Once the appropriate settings have been selected, the **Continue** button should be clicked and the settings saved by choosing **OK**.

The Data Collectors section

Click on the **Data collectors** button or hyperlink in the study checklist to go to the data collectors section.

Data collectors are the people who will actually ask the subjects or make measurements to be recorded into the system. In this particular study, the **Types of data collectors** will typically by **Doctors** and **Nurses**. They are likely to be well practiced in these techniques so one would expect the **Estimated degree of protocol compliance** to be **Fair** and their **Technological literacy** also to be **Fair**. For the purposes of this tutorial we will assume the **Linguistic abilities** to be primarily **English (United Kingdom)** and **French (Standard)**.

Once the appropriate settings have been selected, the **Continue** button should be clicked and the settings saved by choosing **OK**.

Figure 7   The Data Collectors

The Data Entry Staff section

We now turn to the data entry staff. Click on the **Data Entry Staff** button or hyperlink in the study checklist to go to the data entry staff section.

In the case of individuals measuring data and entering it directly into a computer, these individuals are considered both data collectors and data entry staff. In the case where information is being transcribed from paper forms into a computer, the data entry staff are the individuals performing the transcription.

In this particular example, the **Data Entry methodology** includes **Direct to StudyBuilder Field Edition** (the name of the product used to collect data in the field). This will probably be the case for people using Microsoft Windows CE palmtop computers in front of patients. The **Transcribe from StudyBuilder form** will also be applicable as the program will be producing paper forms for data collection and experience suggests that many individuals providing data for a registry prefer using paper.

We assume once again that the **Estimated degree of protocol compliance** is **Fair** and that the **Technological literacy** of the subjects is also **Fair**. We also assume that the **Linguistic abilities** of the data entry staff are the same as the data collection staff, that is **English (United Kingdom)** and **French (Standard)**.

Once the settings have been selected, click **Continue** and save the settings by choosing **OK**.

Figure 8 The Data Entry Staff section

The Data Collators section

Click on the **Data Collators** button or hyperlink in the study checklist to go to the data collators section.

Data collators are the individuals who will manually check data entered into the system for errors that the automatic checks do not detect. For a registry, the **Collation methodology** might often not be applied until final analysis, however best practice suggests that a continuous **Review and query** process should be in place. We will use this methodology for this example and the appropriate options should be selected in this section.

The **Technological literacy** and **Linguistic abilities** should be set to the same values as in previous screens.

Once the appropriate settings have been selected, click **Continue** and save the settings by choosing **OK**.

The Data Analysts section

Click on the **Data Analysts** button or hyperlink in the study checklist to go to the data analysts section.

For a standard easy to import and analyse, in the **Data repository** section, choose **International Data Standards Consortium CSV file**. Click **Continue** and save the settings by choosing **OK**.

Methodology

Having finished specifying who the various participants in the study are, we now turn to the methodology that will be used to actually implement the study. Once again, a series of sections should be worked through to define the study structure.

When will data be collected

For this simple registry we will record subject information at a registration visit and once a year at an annual review. Figure 9 shows selecting these options.

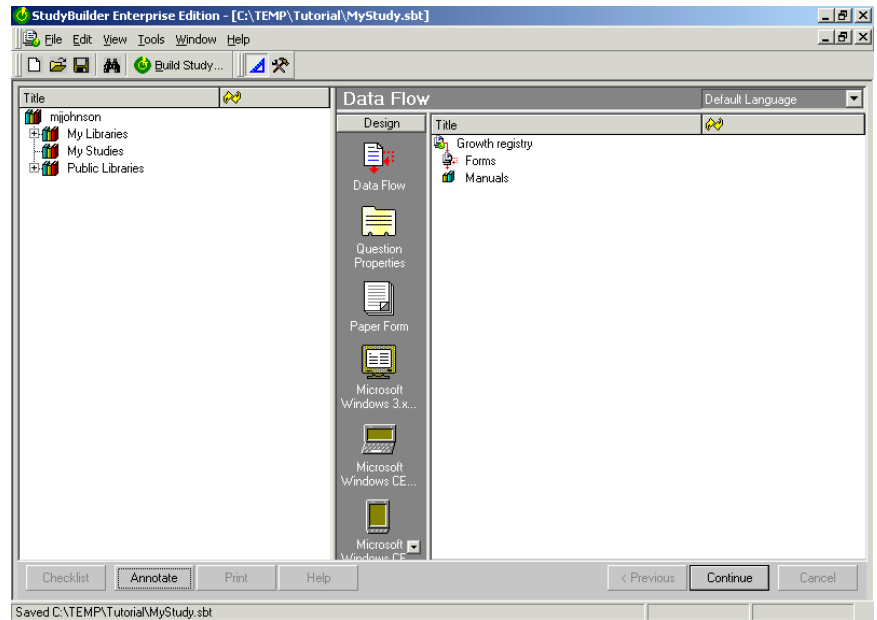**Figure 9   Specifying when data will be collected**
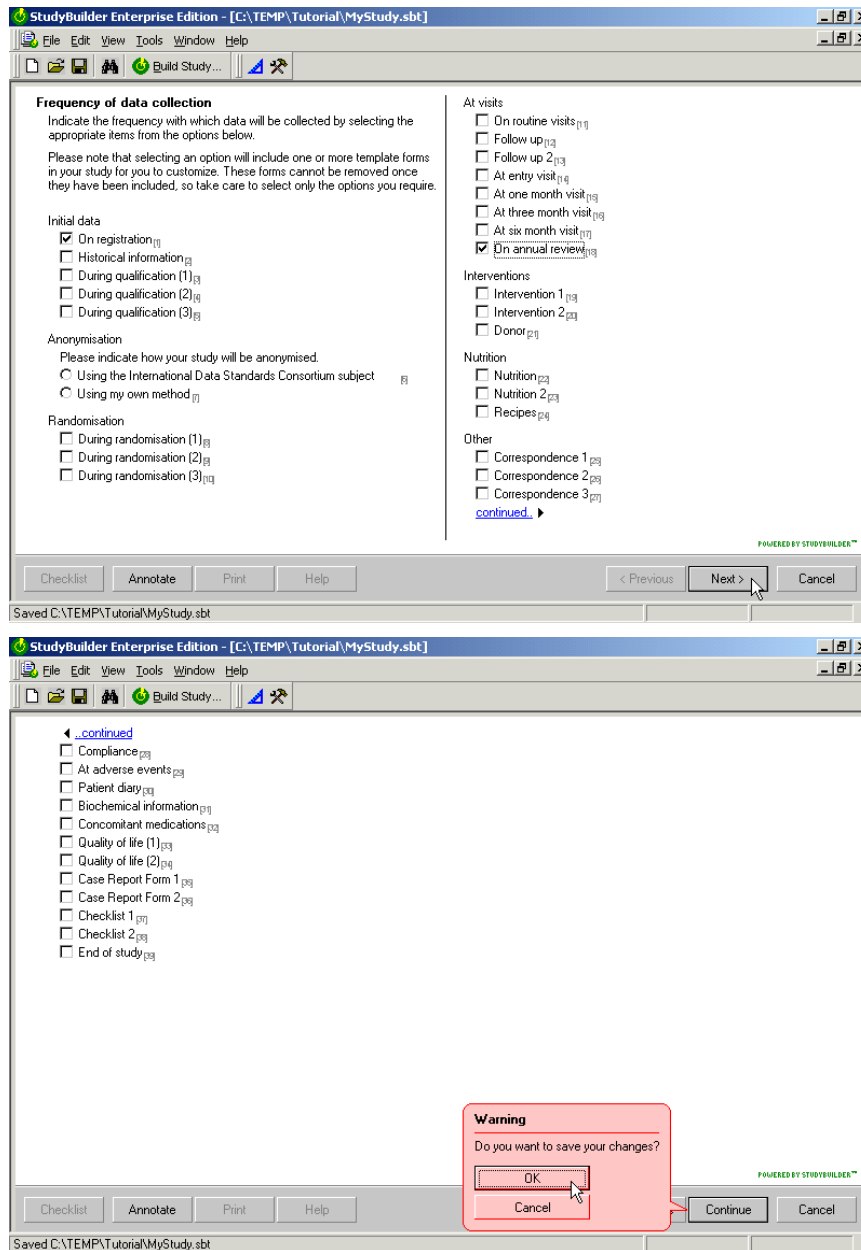
What data will be collected

Next we will actually select what data will be collected at each visit. In the main study checklist, click on the **What data will be collected** button or hyperlink. You will see a screen similar to that shown in Figure 10.

Figure 10 What data will be collected section

The left hand side of the screen is the question library from which we will drag questions to be asked onto the right hand side of the screen that is used to display the order in which questions will be asked and to preview the materials.

On our registration form we will assume that we want to ask the following questions:

- Subject number
- Given name
- Family name
- Sex
- Date of birth


and on the annual review form we will ask:

- Date of visit
- Height
- Weight

The next step is to select these questions from the StudyBuilder Standard Question Library and drag them on the form. First of all we need to identify the forms so that we know where to drag the questions.

Double click on the 'Forms' object in the data flow in the right hand window. You will see a list of forms displayed. Most of the forms are screens that will be displayed for administering the study and can be ignored for now. Find the form labeled **Register subject** and click the right hand button on your mouse. A menu will appear and with the left

hand button on your mouse you should select **Expand All** as shown in Figure 11.

**Figure 11 Expanding the data flow of a form**
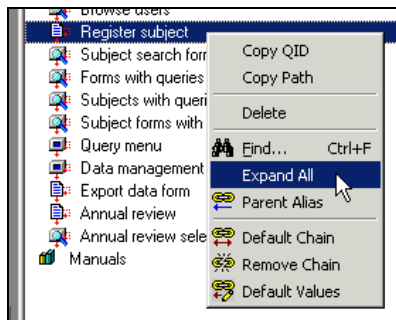
You will then see a list of the questions already asked on the form (Subject number, date of visit, name). We want to add Date of birth and Sex to the form so in the left hand window, double click on the following:
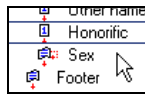
Public Libraries >> Libraries >> Standard Question Library >> Indexes >> Templates **>> Demographic details >> Gender >> Sex**

Now click on the item **Sex** in the left hand window and drag the item over to just above the section **Footer** in the **Register subject** form on the right hand side as illustrated in Figure 12. Let go of the mouse button and you should see the results shown in Figure 13.

**Figure 12 Dragging a question from the library onto a form**
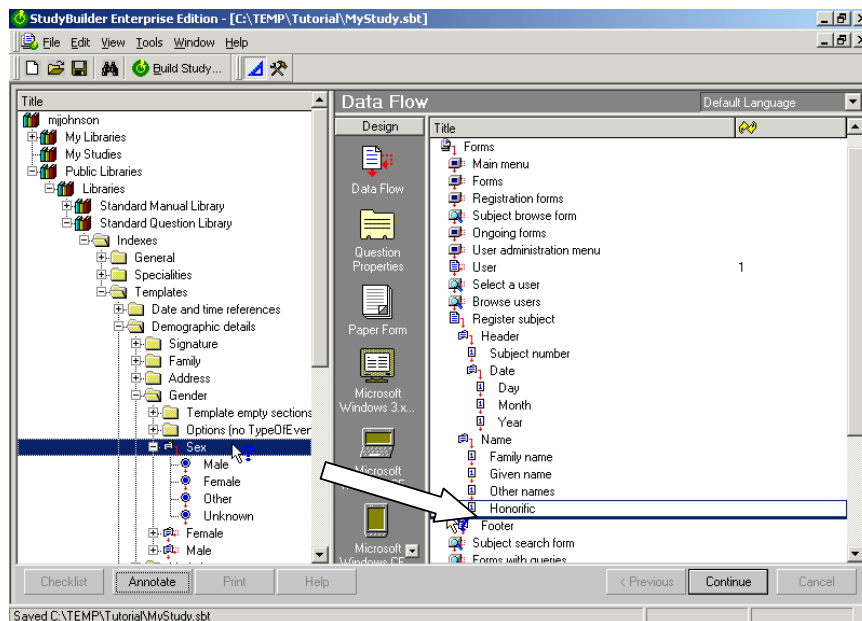
**Figure 13 A question dropped onto a form**

Now do the same for the **Date of birth** question stored in: **Public Libraries >> Libraries >> Standard Question Library >> Indexes >> Templates >> Demographic details >> Birth >> Date >> Date of birth** and the final **Register subject** form data flow should be as in Figure 14.

Figure 14 Complete data flow of the register subject form
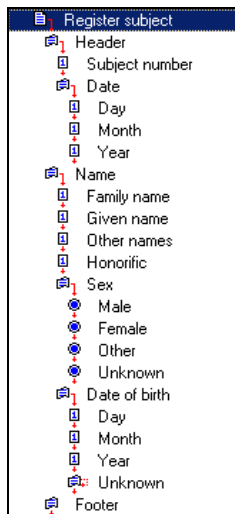
To preview the paper version of this form, click on **Register subject** in the data flow and click on **Paper Form** item in the **Design bar** as shown in Figure 15.

Figure 15 Previewing the paper form
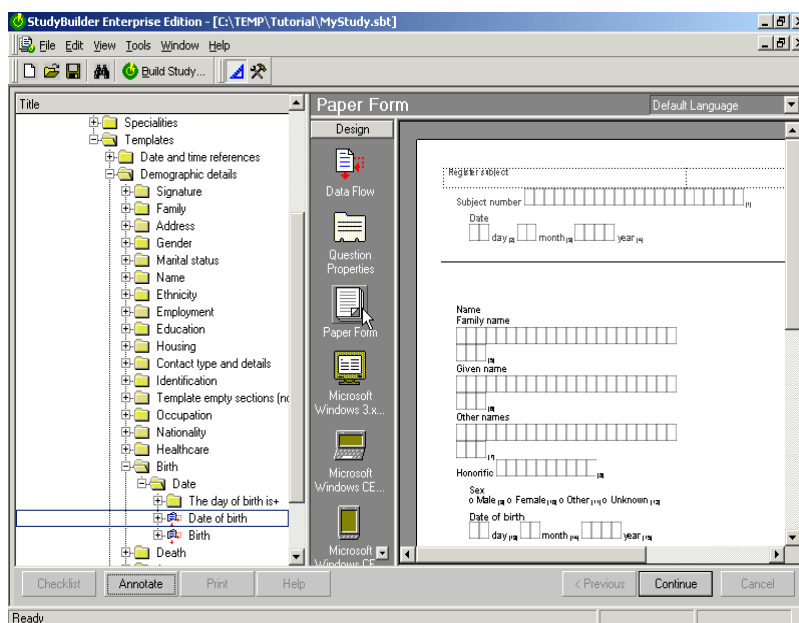
Click on **Data Flow** in the **Design** bar to return to the data flow and find the **Annual Review** form. Click on it and then right click and select **Expand All**.

Now add the following questions from the standard question library into the annual review form as you did before:

Public Libraries >> Libraries >> Standard Question Library >> Indexes >> Specialties >> Growth >> Growth Registration >> Height

Public Libraries >> Libraries >> Standard Question Library >> Indexes >> Specialties >> Growth >> Growth Registration >> Weight

When complete you should have a data flow for the annual review form similar to that shown in Figure 16.

Figure 16 The completed annual review form

You have now finished selecting what questions will be asked in your (admittedly very simple) registry. Click **Continue** at the bottom of the screen and you will be returned to the study wizard study checklist.

Where will data be collected

For this particular registry we will assume that the study will be taking place at two centres, The Hospital, London, United Kingdom (site 1) and at L'Hôpital, Paris, France (site 2).

In the study design wizard, click on the **Where will data be collected** option and you will be taken to a section with three options:

- Add a site
- Review a site
- Delete a site

Click on **Add a site** and you will be presented with a site registration form that you can fill in with the details for site 1. When complete, click **OK** and repeat the process for the second site. This acts as your site logbook.

How will data be recorded

We now need to specify in what format data will be recorded. We want to collect data on paper, on Microsoft Windows 95 compatible computers and on Microsoft Windows CE compatible palmtops. The materials need to be in English and French. In addition we want all users and sites to be able to backup data. Figure 17 shows the appropriate settings for this project.

Figure 17 How data will be recorded at the sites

Who will enter what data

Having specified how the data will be collected we now need to indicate whether the data is first or second hand. For this registry we assume that the investigators will be making measurements themselves. Therefore the **Subjects** section has no entry. In the **Investigators** section we record that they **Enter data directly**. **Data entry staff** will **Transcribe data from paper forms**.

Figure 18 Who will enter what data
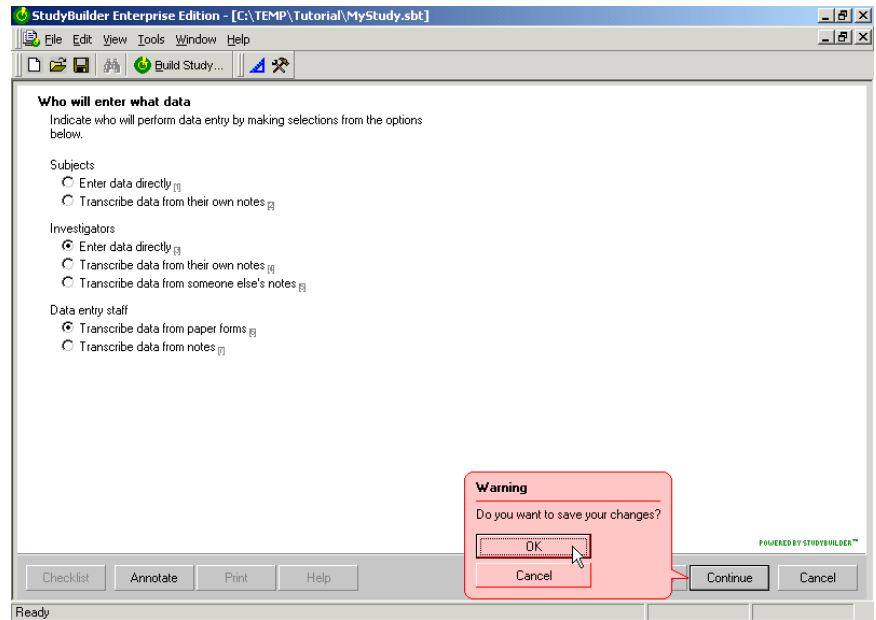
How will data be collated

We also need to specify how data will be collated. In our registry design we have assumed that all the centres will be feeding data to a single point. Within a centre, because we have palmtops and desktops we need to define an extra step where the palmtops synchronise data with desktops that then forward data to the national centre.

At the study wizard checklist, select the **How will data be collated** option and indicate that data will be collated **At a single centre**.

In the **Data collation strategies** section select **Site supply data centre** (assuming that the registry sites supply data to a data centre that then does all the reporting).

You should also select **Palmtops synchronise with desktops** to indicate that the palmtops should use desktops as a staging point for the data rather than sending their data directly to the data centre.

Who will analyse what data

The final step in defining the methodology is to indicate how the data will be analysed. In the study wizard, choose the **Who will analyse what data** option and you will be presented with the options shown in Figure 19.

For this particular study, we will allow **Investigators** and **Analysts** to analyse data by giving them permission to export data. In addition, in the **Documentation** section we indicate that we would like to have a technical manual generated so that written definition of the questions in the study and the validation criteria that are applied to them.

Figure 19 Who will analyse what data
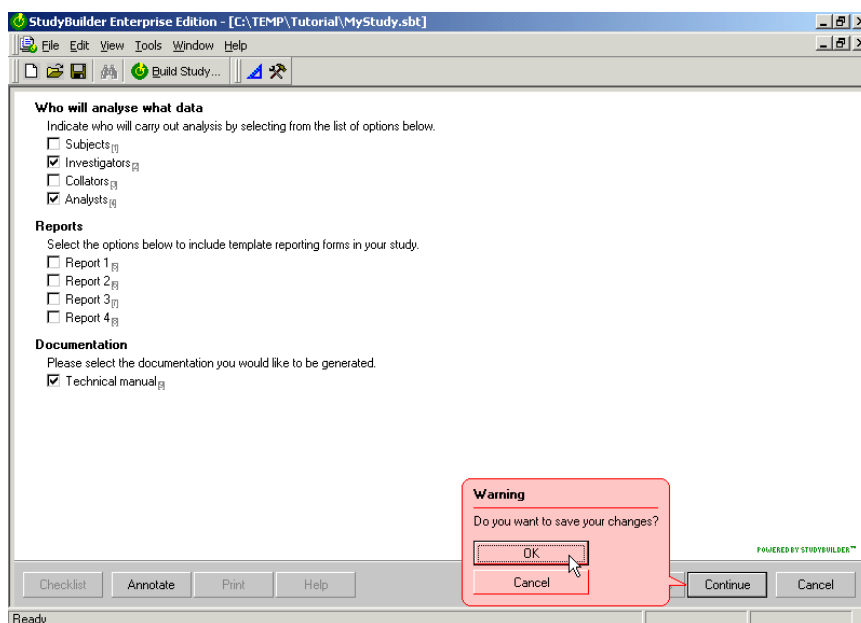
Having chosen these options, press **Continue** followed by **OK** and you have almost finished designing your study.

Visual design

StudyBuilder Professional Edition and StudyBuilder Enterprise Edition come with a number of different templates to allow you to modify the presentation of the forms and manuals that the system generates. For the purposes of this tutorial we will use the default values and therefore do not need to change anything in the **Visual design** section of the study wizard.

Study generators

StudyBuilder Professional Edition and StudyBuilder Enterprise Edition allow you to fine-tune the process that is used to generate studies. This is particularly useful when dealing with very complicated study designs. Because the study used for this tutorial is very simple, none of the options in the **Study generators** section of the study wizard are of any relevance to this example.

Testing

You have now completed your study design. To test that it works properly you should try entering some real data into one of the live previews that the software provides.

For example, we will check that we can register a patient on a Microsoft Windows CE device.

To switch to a live preview of the system you need to switch to the study studio. You can do this by returning to the **What data will be collected** section of the study wizard.

Once in the design studio you need to switch to a preview of StudyBuilder Field Edition for Microsoft Windows CE/PocketPC by selecting the appropriate icon in the design bar as shown in Figure 20.

Figure 20 A live preview of the study on a palmtop
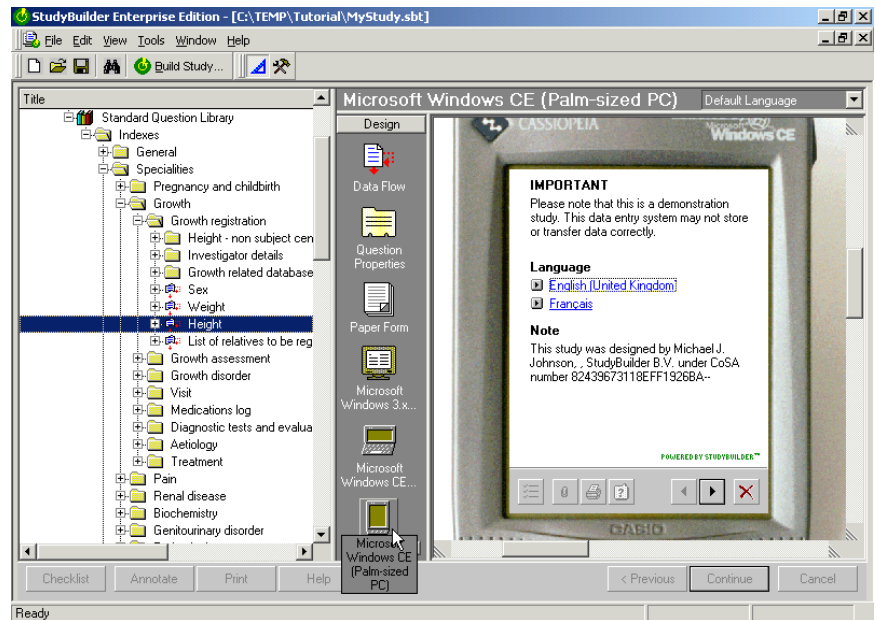
Note that if the preview does not fit exactly in the window you can use the scroll bars to centre the display in the preview window.

Log into the system

The preview behaves as the live data entry system will. For example, if you click on the button or hyperlink marked **Français** the preview will display the French version of the screen. Click on **English (United Kingdom)** to get back.

Figure 21 The login screen in French
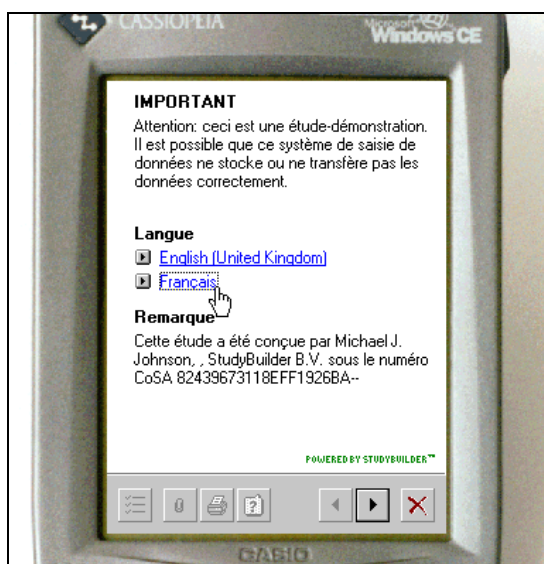
Click on the arrow pointing right at the bottom right hand corner of the screen. This is the equivalent of the **Next** button on a desktop computer and will take you to the next screen. Click **Next** again and you will be asked to supply a username and password. Unless you configure users when you have logged in, it is not necessary to enter a username and password, so click on the green tick (the equivalent of the **Continue** button) and the system will display the main menu shown in Figure 22.

**Figure 22 The StudyBuilder Field Edition main menu**
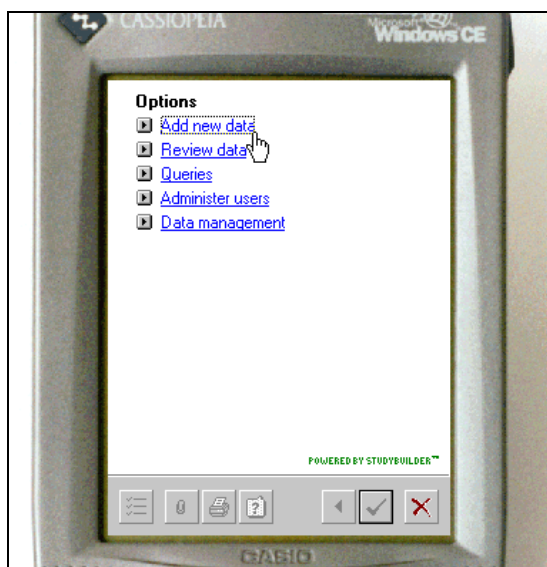
Note that not all studies will have all these options. Only the options appropriate to your study will be included.

Add a subject

Now register a subject. Click on the **Add new data** button or hyperlink and you will be presented with a choice of **Registration forms** or **Ongoing forms**. Click on **Registration forms** and click on the **Subject registration** button or hyperlink. You can now enter data as shown in Figure 23. Notice how the 'deliberate mistake' causes a warning to be generated.

Figure 23 Entering data in a live preview
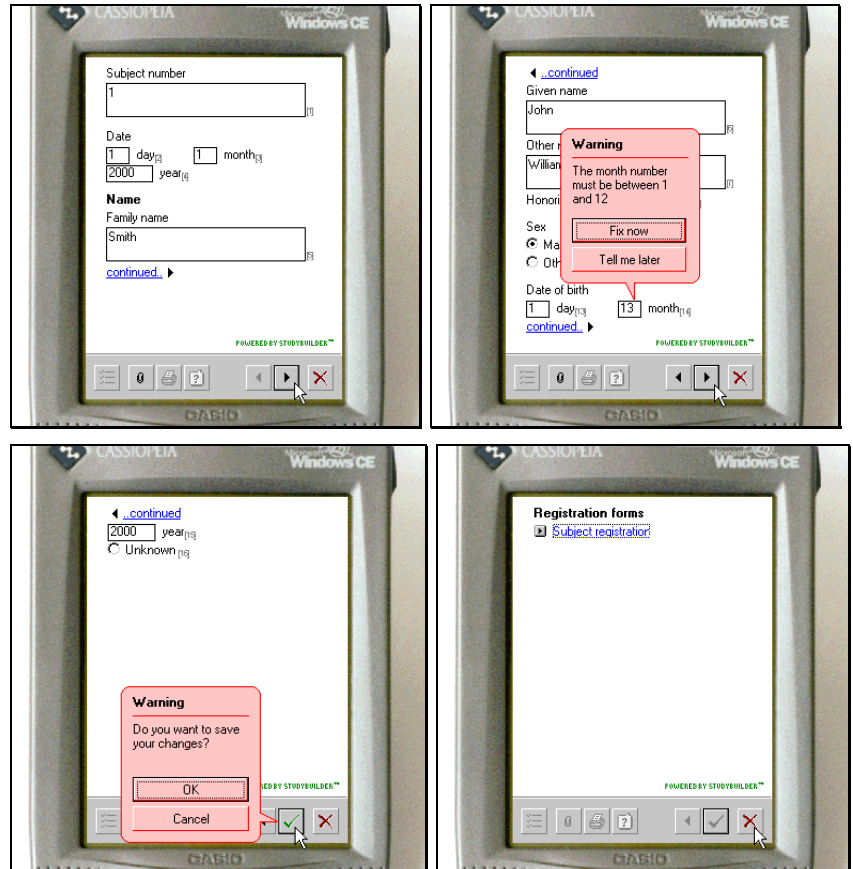
Once the form has been saved you are returned to the registration form menu. Press the red cross button (equivalent to the **Cancel** button) to return up a level in the menu structure until you back at the choice between **Registration forms** and **Ongoing forms**.

Add an annual review

Click on **Ongoing forms** and then on **Annual review** and you will see a search form. Click on the **Show all** button and you will be shown a list of all (one) of the patients in the system. Click on the button next to the subject that you would like to enter a data entry form for and you will be taken to the data entry page. Note that the subject number is drawn with a yellow background. This means that you cannot change its value. You can then enter data for the annual review as before.

The Mission

Eliminate duplication and waste of effort in the design, management and execution of medical research.

The Company

StudyBuilder is an international group of software companies designing and delivering software to automate study design and implementation.

Founded in 1997, the company services a worldwide market from its principle offices in the United Kingdom, United States of America, The Netherlands and Japan. We are rapidly expanding our existing network of local sales and support services so that we can serve our clients even better.

The People

The staff of StudyBuilder are all experienced specialists with backgrounds in academic and commercial medical research and software development committed to delivering high quality affordable systems to achieve our goal.
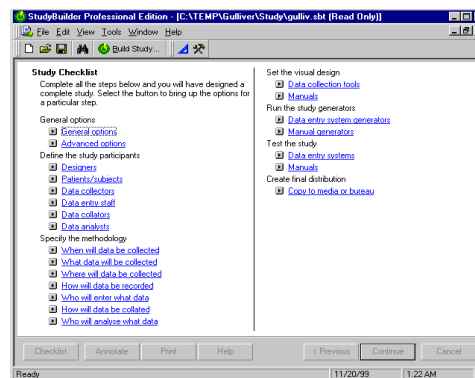
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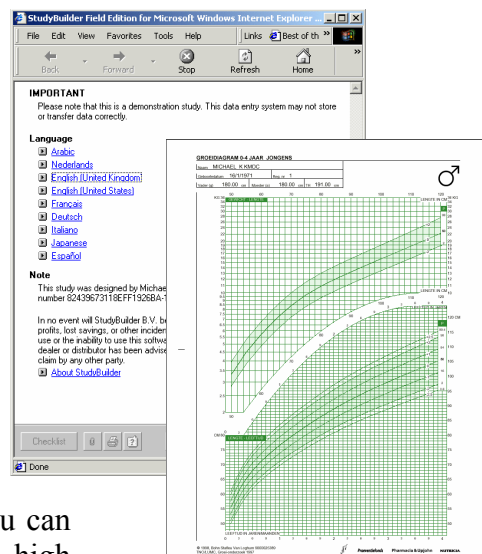
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Conclusion

StudyBuilder represents an incredibly cost-effective way to design and manage studies. We handle the details so that you get to manage the study goals and watch the data as it rolls in. Call us – you could be building studies the easy way within a few days.

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