



Questions about PKS Online™

- Q: How long does it take to get up and running with PKS online?
- Q: Is there an evaluation program for PKS Online, and how does it work?
- Q: How is PKS online priced?
- Q: Are different access levels of PKS online available for analysts vs. QA staff?
- Q: How will Pharsight support audits and validation of PKS Online?
- Q: Is PKS a data and file repository or can you actually run WinNonlin, SAS, S+, etc. within PKS?
- Q: Do you need to be online all the time during your data analysis?
- Q: Can you search across studies or within the specific study?
- Q: Is there a format requirement of the WinNonlin data sheet?
- Q: Is it required to import Watson / LIMS data into WinNonlin before importing into PKS?
- Q: How is PKS application security defined and managed?
- Q: How is data security and backup arranged?
- Q: What is the access speed and what kind of performance hit can be expected when routing through Proxy servers and firewalls?
- Q: Who is the hosting provider? Where is the hosting provider located? How much up-time can be expected from the hosted service?
- Q: What is the typical planned downtime?

Q: How long does it take to get up and running with PKS online?

A: Your instance of PKS Online can be up and running for you to use within less than a week. However, we expect that before going into production, a small validation effort would be required if the system is used in a regulated environment. Pharsight's deployment group offers validation support services that can help you to complete this validation in a few weeks or even less – depending on your schedule.

Q: Is there an evaluation program for PKS Online, and how does it work?

A: For a PKS Online evaluation, customers should talk to our sales team. We can give you access to a specific evaluation instance of PKS Online for some time period.

Q: How is PKS online priced?

A: There is a fixed access fee per user per year which covers access, administration, backups, etc. Depending on your company's specific situation and requirements, there could be an additional cost for the upgrade from WinNonlin Professional to WinNonlin Enterprise and for AutoPilot or PKS Reporter – if you decide to purchase any of these programs. Please contact the Pharsight sales department for details and to learn about the specifics for your company. sales@pharsight.com

Q: Are different access levels of PKS online available for analysts vs. QA staff?

A: We have two distinct levels of access: 1. Full Access users, which can use all programs such as WinNonlin or the Web browser and 2. Restricted Access users, which can only use the Web browser to access PKS Online. Restricted access is less expensive and is designed for reviewers or managers that need to examine data but don't do data analysis.

Q: How will Pharsight support audits and validation of PKS Online?

A: Our Pharsight experts have executed a full validation on the hosted PKS Online system – including a full audit of the hosting provider. Depending on your specific validation needs, we expect PKS Online customers to audit Pharsight as a vendor and to review our validation documentation. As for the necessary validation of the whole system – for example, including PKS Online access and WinNonlin – we are offering very focused validation services through our deployment group at fixed prices. Contact your sales account manager for more details.

Q: Is PKS a data and file repository or can you actually run WinNonlin, SAS, S+, etc. within PKS?

A: The tools are not executed “within” PKS Online – but they load data from PKS Online into a local workspace, execute the analysis and then store results back into PKS Online as a new scenario or as a new version of the same scenario.

Q: Do you need to be online all the time during your data analysis?

A: You only need to be connected to PKS Online while the data are loaded from or saved to PKS Online. When using WinNonlin 5, WinNonlin must not be closed during between the load from and save to PKS Online, i.e. the work needs to be completed within one session of WinNonlin. With Phoenix WinNonlin, you can disconnect from PKS Online, close Phoenix WinNonlin and pick up your work later and reconnect to PKS Online and save the results of your work.

Q: Can you search across studies or within the specific study?

A: There are several methods to search across studies and to extract data from different studies for analysis. With Phoenix WinNonlin you can even use a new concept called Study Views that allow to extract data from different studies and run analysis right on the study view.

Q: Is there a format requirement of the WinNonlin data sheet?

A: Data are uploaded from WinNonlin by using an interactive wizard that maps the columns of the WinNonlin worksheet to PKS Online variables. There are no specific format requirements. However, we strongly recommend to think about some standardization or harmonization when using PKS Online because this will greatly increase the value that you get out of your data that are available in PKS Online.

Q: Is it required to import Watson / LIMS data into WinNonlin before importing into PKS?

A: Creating studies in PKS using WinNonlin is probably the most common way. However, there is a technology that we call PKS Data Connectors, which allows to transfer data directly from LIMS databases or flat files into PKS Online. This is not part of the standard PKS Online system and needs to be developed specifically for each customer and will be sold separately under a time and material contract.

Q: How is PKS application security defined and managed?

A: PKS Online has the same security model as PKS, i.e. write or read access to studies is defined on a user by user basis. The authentication process is based on the Oracle security model. The Internet access to PKS Online uses a SSL certificate (https protocol) with up to 256 bit encryption depending on your browser.

Q: How is data security and backup arranged?

A: Our hosting provider runs several secure facilities in the US and the rest of the world. Access to PKS Online is through the secure https protocol with a SSL Certificate from VeriSign. Our hosting provider manages daily incremental backup and weekly full backups. These backups are saved for 28 days, i.e. after this period the backup files are overwritten with new backup files.

Q: What is the access speed and what kind of performance hit can be expected when routing through Proxy servers and firewalls?

A: The access performance for PKS Online depends on the speed of your Internet connection. We have not seen a noticeable difference between our in-house deployed instances of PKS and the PKS Online which is accessed through our firewall to the Internet and to the server that hosts PKS Online – there were no noticeable delays.

Q: Who is the hosting provider? Where is the hosting provider located? How much up-time can be expected from the hosted service?

A: Our hosting provider is Savvis, one of the largest providers of managed computing and network infrastructure services. Savvis is headquartered in St. Louis, Missouri and has 29 data centers – mainly in North America including California, Missouri, Virginia, and New Jersey. Per the Service Level Agreement, Pharsight promises 99% uptime for the PKS Online service, excluding schedule maintenance by Pharsight or the hosting provider.

Q: What is the typical planned downtime?

A: To ensure the continued performance and security of computer system regular maintenance is required. Our hosting provider has a maintenance plan that earmarks Saturday and Sunday nights from 12am until 5am for maintenance – if maintenance is required at all. Pharsight will post any schedule maintenance hours in advance to all our customers.