PSIXCHANGE
MAKE YOUR DATA WORK

Subject/Item	PSIXCHANGE	Standard Portal	Manual Distribution	Importance	Notes
Method of distribution	Email/fax/courier/E2B	Email/fax	Email/fax/ courier/E2B	●	Available methods for document distribution
Internal efforts	Very low	Medium	Very high	●●●	Overall workload associated with submitting a single document to all applicable recipients
Time per Submission	Super fast	Fast	Very slow	●	Time required for a single submission using the system
Recipients	Unlimited	Limited, e.g. sites only	Unlimited	●●	Recipient types that can be addressed, e.g. Sites, RAs, local and central ECs, CRO, Sponsor…
Cost	Low	Medium	Very high	●●●	Costs include workload for preparation of a document, sending it to all recipients including tracking, oversight and shipment
Oversight	Very good	Intermediate	Poor	●●●	General oversight the system allows e.g. study specific, drug specific, cross reporting…
Compliance	Very good	Good	Low	●●●	General compliance of the system including tracking and acknowledgement of submissions
Traceability	Very good	Good	Poor	●●	Dashboard functionality including reports, charts, or export in Excel sheets…
Auditability	Low	Low	High	●●	Effort to fully audit the process and the actual distributed documents when using a system
User friendliness users	Very good	Very good	Good	●●	How easy is it to work with the system for standard users
User friendliness admins	Good	Good	N/A	●●	How easy is it to work with the system for admin users
Recipient effort	Low	Medium	High	●	Effort the recipient must take to get his document e.g. login required? Manual efforts on receipt? Active document search?
Security	Very high	High	Low	●●●	The amount of effort required to illegally obtain confidential data
Flexibility	Very high	Low	Intermediate	●	Flexibility allows system changes even when the system is fully configured and live
Adoptability	Very good	Intermediate	N/A	●	Ability to reflect current customer processes used for distribution of documents, e.g. including decision making for submission of Events of Special Interest
Training effort admins	High	High	N/A	●	Administrators need to be trainend on administration in addition to standard use of the system
Training effort user	Intermediate	Intermediate	High	●●	Standard users need training for day to day business
Training effort recipients	N/A	Medium	N/A	●●	Recipients need training in case there are additional tasks other then daily communication, e.g. portal use to get to a document
Reminder management	Very good*	Good	Poor	●	Keeping oversight on reminder notification *psiXchange can escallate reminders to CRAs
Escalation management	Very good	Poor	Poor	●	If a document was not received (e.g. fax turned off, mailbox not reachable) is there a way of using an alternative method for submission (automated)?
Cover letter creation	Automated	Manual	Manual	●●	Is there a way to modify the cover letters accompaniyng a document?
Support of multilinguality	Very good	Medium	Very good*	●	*depending on the available staff knowledge different (local) languages of notifications and cover letters
Maintain recipients	Optional	Yes	Yes	●●	Recipients data must be accurate all the time to ensure proper distribution of documents. Can this be done within the system (within company for manual distribution)?
Maintain reporting requirements	Optional	No	Yes	●●●	National reporting requirements need to be up to date to ensure compliance. Can this be done completely within the system (within company for manual distribution)? company for manual distribution)?
Integration of client systems	Full	No	Partial	●●	Is a communication with available systems possible, e.g CTMS, Safety database, regulatory compliance system…
Supporting local forms	Yes	No	Yes	●●	Some recipients require additional local forms to be added to a document. An example would be the CTIMP Safety Report Form that is required by UK main Research Ethics Committees
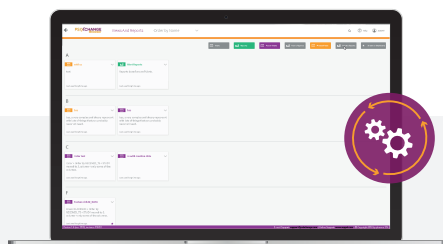
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