

eCTD is not just a software challenge!*

VS

Decision criteria for any eCTD software:

1. How much experience do you have with eCTD?

Some vendors expect you to know everything about eCTD already.

- What is document granularity?
- Why do I need bookmarks and hyperlinks?
- How do I establish my electronic gateway account?
- Where can I find more information?

2. Will your future eCTD vendor be guiding you on areas such as:

- Document readiness?
- Additional tools and technologies you should understand?
- Submission compliance?
- eCTD basic concepts?
 1. What is metadata?
 2. What is a submission versus a sequence?
 3. What does lifecycle management mean?
 4. What is a study tagging file?
 5. What are node extensions?

Reasons why to chose Cunesoft:

1. We guarantee your success

- Call or write support as often as needed.
- Submit as many sequence as you like (worldwide).
- We provide online live training.
- We help you with questions about the overall process in addition to how to use cune-eCTD.
- We guarantee your eCTD compliance!

2. We stand up for your missing knowledge

We have found that over 90% of our support calls are NOT related to the technology itself... they are almost always about the questions starting with:

- How?
- What?
- Why?
- Where?

Other vendors provide tools – – Cunesoft provides success

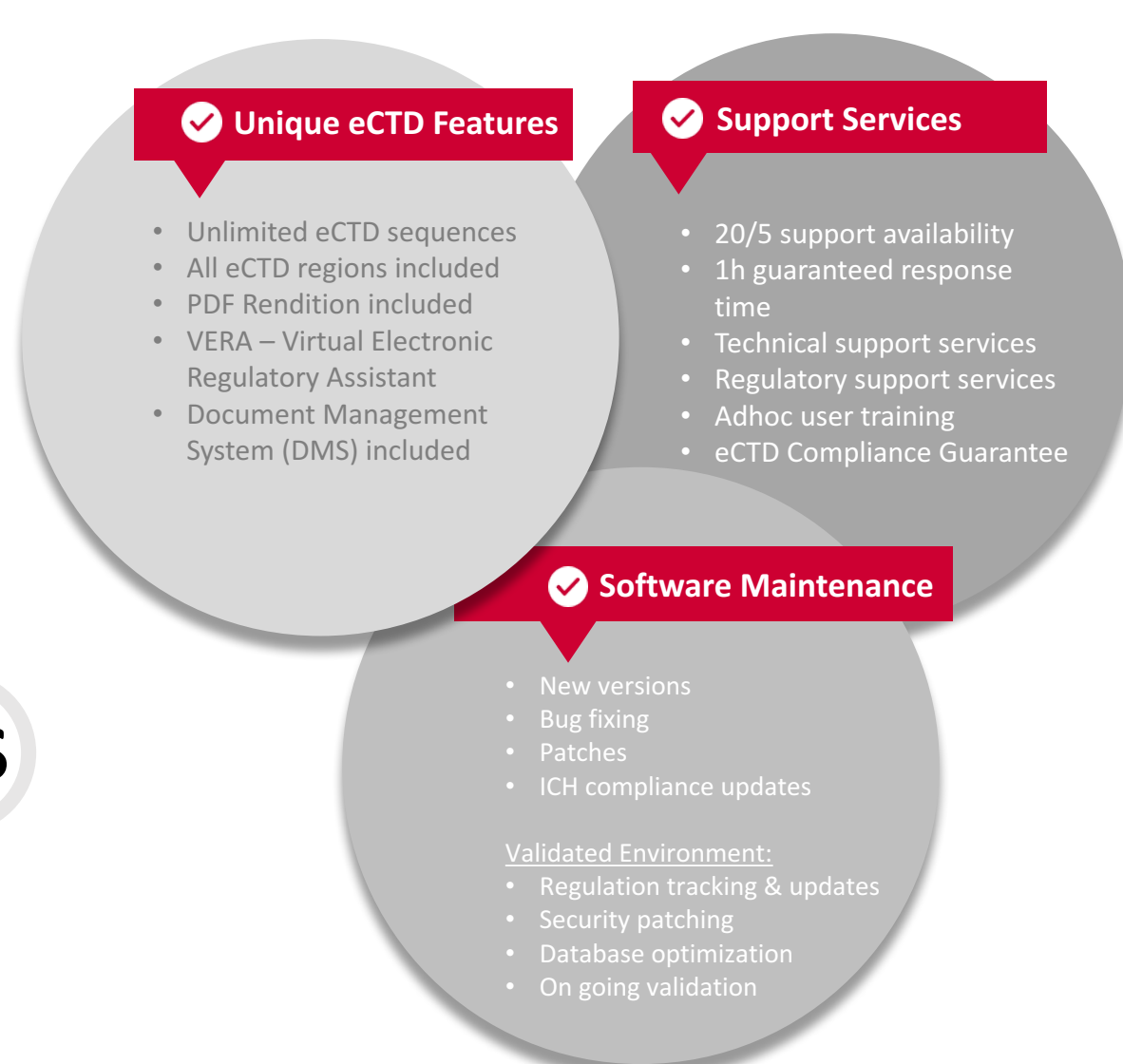
INCLUDED (only) Software

INCLUDED Software & Support

So many software suppliers are happy to offer their technology at a very low price without considering your needs for successfully creating and managing the entire process.



VS



Important Software Features to check

cloud/on premise	?	Cloud
All Regions of eCTD incl.?	?	Globally included
Number of eCTDs limited?	?	Unlimited
ICH Update included?	?	yes
DMS system included?	?	yes
Backup included?	?	yes
Regulatory Support included?	?	yes
eCTD Compliance Guarantee?	?	yes
Readiness for future requirements (i.e.HL7) ?	?	yes
eCTD 4.0 ready?	?	yes
Integrated Suite of Software offered?	?	yes
Is "Software as a Service" provided?	?	yes
Is a multi-tenant architecture to save costs available?	?	yes
Is an eCTD importer included, which updates all data to the right format?	?	yes
Can you share submission documents with not users?	?	yes
Is the support fast enough (1h guaranteed response time)?	?	yes

