Towards a Global Regulatory Dossier Framework for Veterinary Medicinal Products...

> Training Seminar for Focal Points on Veterinary Products for the Africa region

> > (English-speaking Africa) 7th cycle

23-24 FEBRUARY 2022





Prof Dr Erik De Ridder HealthforAnimals Belgium

Starting Point: some history

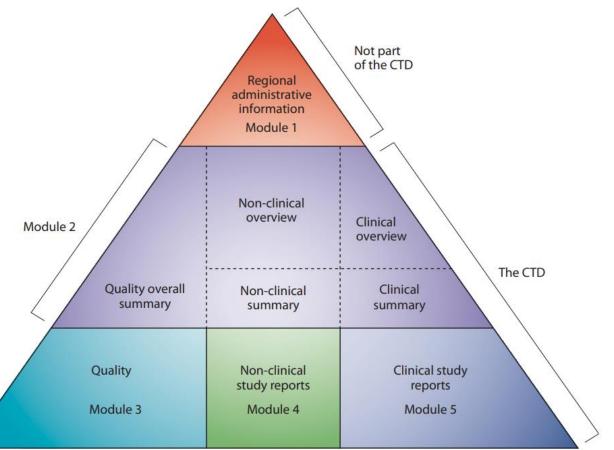
- Evolution:
 - ICH agreed in 2003 to a CTD or Common Technical Document; later e-CTD
 - Vet agencies in several geographies can accept parts of dossier in "human" CTD format
 - others do not accept this
 - Vet industry and vet agencies reluctant to adopt CTD, also because e-CTD would be beyond capabilities in the veterinary world





The CTD triangle of ICH (July 2003)

- 1. Regional admin info
- 2. Summaries & Overviews
- 3. Quality
- 4. Non-clinical studies
- 5. Clinical studies



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.





Starting Point: some history

- Evolution:
 - ICH agreed in 2003 to a CTD or Common Technical Document; later e-CTD
 - Vet agencies in several geographies can accept parts of dossier in "human" CTD format
 - others do not accept this
 - Vet industry and vet agencies reluctant to adopt CTD, also because e-CTD would be beyond capabilities in the veterinary world
- "Hypothesis" for vet products: several different dossier structures exist globally





Starting point: Analyzing current veterinary dossier structures

- HealthforAnimals compared dossier structures for pharmaceutical VMP in 8 geographies:
 - Camevet, China, EAEU, EU, Japan, South Africa, UEMOA, USA





Analyzing 8 national or regional dossier structures for VMPs...

a high-level overview

Halian In Stalianal Values 50	i. Western African Januire UENOA UENOA Parisi Res 2005 MUZ Presentern Res 2005 MUZ Presentern	are ald IPAN Glabal descends	EAEB (E-+A-i Ei- B-i) DOSSIEB	Jaganeer Pharmaneelinal donaire	Bailed States Dessites for CTH Regulated products (pharmaneolisats)	Sualk African Dala Bryairrarala far Slaak ovardira	China Pharmanalina I danning Pranting and gravity and initial state 2005
	Ro. 2011 HUZ House Part I. Summary of the domains	Administration Bata Sections	1. General Descendation	General Summery : A suppreheasing numbers of the duration.	Part To Paladdeenerstation bastaded	 General Information Person of application. 	Part I. Grandal damanda and information 1.1 — Application for a for a former, despression (Caspire)
IA Administration	In Administration	4 Product Trade Name 2 Classification (official one salig)	1.1 Administration data 1.2 SPC	Original discovery of deay, and line of our in farrige analytics, etc. same sink	Saning yn d Saning yn All allwy anwy inniol dala gwar allol, inniol ing pabliaked lliwalare (if webraal) Saning yn Historaeth gwar allol allwir a al yr anhailled andre an llwy baking a webin.	L. Popular approxim	1. 8 May loading form for order increasing registration (2 appire) 1. 4 Product come 1. 2 Main Color Store Second
10 SuPCELSANDing Detailed and willing termining 10 of anality feature tailing		2. Classification (affinistion only) 3. Regarding relabilishment (ID and OP)		 Barrowski Joseph Construction and Distance and Distance and Astronomy 1. Physical Astronomy Science and Astronomy Construction and Astronomy Constructin and Astronomy Construction and Astronomy Construction and	 Amilantic att informating queues and a lattice and get and milled and exclusion to excluse tradition Amilantic Pharmaneneigitame data [16 per data appended excline in any queue phy]. 	2. Antification of the new section/any and	1.2 Administration descende 1.2.1 ONP of API
 A Administration data B Sub C B Labelling De De Di Labelling C ad guality dessavelation ad auforty and evolution C advantability De Label and evolutionary De Label and evolutionary C ad efficient dessavelation 	IC Especia reports Part II Anality	3 Requesting establishment (ID and OP) Hanne fundering establishment (IF Cyconics of in manifest	1.2.2 Lakelling & Hunkings 1.2.3 Hannfanlaren GHP alalan	 Data an physical, historical and shewing properties of active inperdient (e.g. 0.4 data an determination of alreadore. 	Adminis Phermanniqilanor dala jif pendual appended earlier in ang pengeaphy). Deallila	1. Perfectances	1, 2,4 GMP of API 1, 2,2 GMP of API articles alle articulty also and alle GMP should be arounded!
IC descendation Detailed and writinal summary IC of offician descendation	Expert Report		1.2.3 Handratarres GHP allos 1.2.4 registration alute solution EAEU arter MPI	 B.3 data and determination of a transform; B.3 data on physical and a kerninal properties; B.3 data on physical and a kerninal properties; B.3 data on physical and a kerninal properties; 	Reality 3.2.5 BERG SHDSYARCE 3.3.5 General Information API	 Product summary. Patt sector algorithm of explored in a final sector of the sector of th	1, 2,2 OFF of FP (or FP) (or loanse offer princing, also part with GPP should be provided) 1, 2,3 FSC/OPP 1, 2,4 Statemart of the pairwise and loaksingers makers and on pairwise informations
	Compacifies / Dessay form He Physical descloyers			11.3 dala an appetition for and both welling, etc., for deep naturates and pendenty fin. 11.4 In altern a limiteration effect in some of antimizeration (HIC).		9. 9. – 1983 og sinderlinn og orgånsellinn forder og sinder og sinder og sinder og sinder og sinder og sinder 2. – Gerlinnelsen of sinder og sinder og sinder linner (forsenladed) 2. – Ørger med halver sallsen af taket for til in Englisk (ser forsenladed gankape i sære efter samplete 1. – Ørger som efter sallsen af taket for til in Englisk (ser forsenladed gankape i sære efter samplete	1.23 Experient of the palents and beats increasing on an and an palent information of the palent information of the palent in the statement of the palent in the palent in the statement of the palent in the palent in the statement of the palent in the statement of the palent in the statement of the palent in the palent in the statement of the statement of the statement of the palent in the statement of the statement of the palent in the statement of t
Part II Analila	IIA Pharmaceutical development Description of the	2 Logal and Administration dessention			1.3.5.2 Hansfaaler: API		
Part III Anatila profilestor IIA mentilestation sector filestor sector filestor	IID Process satisfaires Control of alcoling materials	7.1 Hamfalaring agreenals	2.1 akarasleristins and properties	11.5 Environmental vink announced.	5.3.5.3 Characterization AP1	7. Proposed South Officians paskage increditionsplete laket	Coefficient Documente activit like primary particulary material and container in qualify 1.2,5 medical manufacturing
faulter, resigirals, alber	IIII Pharmacrolical development Devancipations of the manufacturing actual IIIP Pranna actualization Contract of starting materials factors actualization Exclusional IIIC Packaging materials	7.2 Paurs of Allerary.	2.4.4 Characteristics of the VMP	III. Hansfalleringwelled	3.3.5.4 Cambril of Deep Schulzers	 Examplicatellocation for HCC's Scheduling Constitute (Schedulars)) 	1.3 Internations and particle at the product development
110.1 animali 110.2 martifaliar medianters	IIC Packaging materials Specific measurem is present IID TSE learninging	7.2 Passer of Allarang. Extablishmed Linear of the	2.1.1 Characteristics of the VMP 2.1.2 sharacteristics of AP1	III. Haanfaalariaguellad III.1 Denambalaner 1891	3.2.5.4 Control of Drug Schulzene 3.2.5.5 Reference Standards on Materials API	 Enruption believe from the MCC's Saledating Counciller (if relevant) Automathelity for GHO insertionals from the Gravita Resource Directorals (DaA). 	Is a factor of the second s
IIA.2 quantifative particulars		7.5 Handashare Tar inpuried products: Harbeling Bullyringling and Ferr Sale	2.1.2 akaraderialian af met	III.1 Desqualations (RPI)	1.3.1.5 Reference Standards or Philorida AP1		1.4 Experiespectical adia (CHC and presidential and atomical part
IIA.3 Development Pharmaceulium	Canderal Irada na internanti ate producta Cantend Irada na Itar Statuted III product St.ATRI, testa Bulliere anticarana Tar Statuted product	7.2 Process of All Interacts 7 Ball All Interacts 7 Ball All Interacts 7 Hand Salares 7 Provide Salares 8 Hand Salares 9 Hand Salares	2.1.3 physicandromael / biological properties of 10P1	III.2 Product wavefacturing wellow and process control	5.2.5.8 Container Clauser System API	 Approach believe from the Animal Health Directorate for registration of a stack remoty for Controlled Directors status. 	1.5 SPC & Labelling of annales of avigin
110	Castral Irals on the Sixtabed III product	Austily Sealines	2.1.4 krief laninalaginal akaranterintian af AP1	III.3 Carliforniand participan	5.7.5.7 SLARRIN (4P)		
Control of starting	Statility tools Reflects and also are The Solided gendest		Denne iplica of phone actualized development finalization accussifies, justification of above of 2.2 ingentically, dampe form, primer particular 2.3 Development of the accussional actualizations	Data an alability of the draw ashe have and the finished product [e.g. data as have			
IIC IIC.1 ended of alarding ended alice adaption	116 Inneral-Milly Part III Safety & conidan Ionta	 Pharmanentical form Complete grafitation-grantitation Specifications and numbershapf Complementation 	2.2 ingerdirate, danger farm, primere pankening 7 2.3 Description of the manufasturing process	Data an atalistiq of the deep anterformer and the finished pendent (e.g. data an long- V. formular approximation an ensure least data an anneless time least etc.) Data and Sofeta [16]	5.2.P DENG PRODUCT 5.3.P.4 Dennelpline and Compacilian of the Deng Pendual	0. Pharmanentinal Data 1. Antine Pharmanentinal Ingendicul:	Part II - Forenear order to Data 1.2.2. Sector 2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.2.
IIC.2 Control Enripticate	Espeel Report	11. Spraifications and analyzed and 11. Cornels anaposeda	8.4 Canton for a los filos productos de la constante de la constan	rala VI. Dala an anale laniaily	S.J.P.2 Pharmanella ID configured		are also id provide the additional every and data for patymership form releation and 0.0 application
Container-stancer appleas HC.3 For API and Pinished Pendent minisher of high ind	III & Safely Irala		2.5 Control of Ficialized product	VII. Data an ank and c and alcount famility (e.g. Repeated administration famility)	3.3.P.3 Handalare	1,1. IHH assort Chemical Hannel/CAS Hat/Approxed/falsenalismally compared name/Commence	arada 11.3 development, apentification, teal arthud, possible imposition or after hyperaturla,
ariqis final arti Abreaterialian far arti beaka		Pradual accordingly reasons					Compactifies and meansfacturing of the Statistical product; success of environments and 11. 10 - approximations
	Professions of Irals		2.5 Stability & Philippe I was a second as the first spectra	VIII. Buts an openial famility and as	5.3. P. 4 Caultral of Europicals	1,2. Empirical formula.	II. 11 apriliation
Control Irola on IID Salesardiale products	Presine identification of the matalance 10 & 1 antice (pendent	 antitier Specifications and analysis for Sinisted product [Districted product [Distrited product [Districted product [Di	2.7 Other information	VII.1 esternicie	3.3.P. 5 Cauloul of Press Pressland	1.3. Helmeler winkle	II. 18.1 Palak formular and formular descharmed
		10. anomalistication (i.e., 50, 250, 500 mL) 43. Presentiations (i.e., 50, 250, 500 mL) 44. Specifications cale participation and participations 45. Specifications (i.e., 50, 250, 500 mL) 46. Specifications (i.e., 50, 250, 500 mL) 47. Specifications (i.e., 50, 250, 500 mL)	2.7 Obernstein 3. Desenvelation on the safety of the one of THU 7.4 Desenvelation on the safety of the ore 2.4.1 Desenvelation of the alter solutions	P VIII.2 Incidentialities			 T. B., T. Markovanicz and terminator development. Manufactures preserves (including flow shall). S. Paramonical and the preserve including flow shall. S. B. Sancer and scalar development including the preserve including the preserve including flow preserve including the preserve including th
HE Statistic product	III A 2 PK/PD III A 3 Tainaladainal aladira III A 3.1 alaqte dans taniniq	194. Specifications and parkaging anotest 195. Stability stadies		19 VIII.2 Instalieritation 19 VIII.3 Piterport VIII.4 Requirementization for out withing as 801 salar.	5.2. P.S. Deference Standards or Halveiale 3.2. P.J. Cadalane (Surano System 3.2. P.J. Stalling	 9.4. One constraints of insure and palamerships where applicable. 9.5. Structure classifiers of these Characteristic Estimations, 1999. 9.5. Provide insurable cardinations and deep colations produced (FranceSter). 	
	III A 2.2 ergeal daar laainilg	St. Statistics (Capitalities)	5, 4,2 Domeripline of the VMP	IX. Dala an largel animal nafely [GLP]	3.2.6 APPERDICES	1,7. Device physical and alreaded progration. 1,4. Spracify a biased based of an APR is been supported as a minimized for justifying the factor for in- tensor symptotical and a physical which is the factor physical and a biased on a single in a biased.	II. 18,5 BSE/TSE Statement
IIG Olber information III Safely	III A 3.3 Internation in the Large Lagranies	Effiana aralian	5,4,3 Indications	Pala on pharmanological aution	5.2.0.3 Heart Earlyinda	 Specificalized rates are been able to the phone and calibration reports of analysis we bede. 	11. 11 Control Indone like Galaked gendent
Safely	III A 2.4 repeatenting families	17. Efficançaladira	3.1.4 Pharmanelogical data 3.4.5	X. Dula un officializzarea	5.3.R REGIONAL INFORMATION	1,3. Coefficients of analysis second balance	II. 11,1 Specification of PP
- III & Safely Irala III & abt Pressranan of the tr		r 19. Une in Castling and marketing and reason 19. Application with a land administration	1.4.5 Teninelegiest data	XI. Bula an general pharmanalogy XII. Bula an advanced in a distribution, we take in a structure in	Safely S. 1 Target Mainal Safely	1. 1. API associations with CMP assistants 1. A If wellight API association Comparation Indianagements Confidentiation of wellability	H. 1952 Tool arthodo and arthodo antidatina H. 1953 Bachdia (arthodo antidatina
Presine idealification of the							
III A akt 1 anliar 2 product	man.e. Inc. 1.2 Annythin of the taplast and Incomplete of the taplast and		1.1.7 Assessment of environmental risk	XIII. Effects angel flore in the same of an anti-size shiel agent.	5.1,8. Deaff Labelling lead coloured in nafely	1,11. Stability data of API, including exclusion	0.42 Justification for modest flow or builting and finitization determination
III A Ch1.2 Phormanology	laanaalaalaila Miseakialayiasi peopertien of eesidare Mikit Okernatiana in kansan Janee	Estraporary proparation products 21. Data to proparation in stability	/				
Ch1.2 Phoreandage	III A 4 Okarradian is kanan jaarr	21. (kom få perspärer, former allability)	3.2 Resider dessarabilities	XIV. Buts an exactly of attained totals (GCP)	5.4.4 Margin of Safety in the larget species (generally a 4, 5, 50 study)	2. Permitation:	11. 19 Reference education data (Avigin and perifficial inc) for analytical actual of peri Statistic periods and Communications and perifficial inc) for analytical actual data (a) Battern advictment (Borean data) (B), evaluation of the statistic perifficient data (a) The Gindrick periods (Borean data) (B), evaluation of the statistic perifficient data (b) (B). 44 International (B)
III A.Ch12.1 Pharmandananian	IIIAS Exclusivity	Danage 24. (Dune, internal and duration)	12.1 Photoschiseline		\$12Turindua	2.1. Teade same / Brainfored same.	References and a second Stream alability, and there stability and Manufactured at Align The Stabled gradient (Stream alability, and Harr stability and Manufactured et alability 11.44
	III D Braidar Irala akapter I Performaner of Irala		All Basisse surgiable learts	XV. Dala un residue alude (GLP)	5.4.5. Belanad Pharmaniaginal utativePK/PD 5.4.6. All families information evoluted in a field		11. 15 – Janif Giadina and analysis any pintang pankaging malerials ar analaineen far finiske 11. 15. – Order for finisked aradiaal
						2.2. Demages forms and some of administration sequencing installed, laying the R.D. Devention interpolation and, applicability and wall. Communications with a provide the provided of the programmers for preserving sets. Junct survey and to save, with and saved gives in the applicability for all.	
III S. Chi	Holabalian and evolution Hilb Kinelian	22.2. Pendasta phormanologicamian Jammara arrayalla	al "4. Efficien deservale		5.4.4.1 Oliver requirements if relevant: humanitariaily	application form).	11. 15,2 Maatee kalak eenneda
III &.Chi5 repeat data fasticity III &.Chi5 Information in the target operation	IIID 1.1 PK (ADHE) IIID 1.2 Deptetion of evolution	grannall, incompatibilities and pharmanological 22.3. Alexanism 23.4. Projections and secretary is a simple	4.4 Education • 4.2 Clinical and prevalisinal shadires. Taberature		5.1.1.2 Olivera experimentale if references Development of consistence 5.1.1.3 Olivera experimentale if references Reproductive Trainitia	 Detail the gamegame of each inpedient in the formulation 2,6. Homotochecky formula 	11. 15.2.1 Executed producting balak execute 11. Inspection [Insting] balak execute
	III0 1.2 Depleties af ernidere	22.5. Astropation 22.4. Pointering and surveduer in astimute	* 4.2 Clinical and prealizing tabalies. Taberanier		S. S. A. L. Ollova requirements if relevant: Reproductive Taxinity		II. Inspentias (Iradias) kalak reservés
reproduction too including	1119-1.5 Reaider analytical welland	22.5. Human pairwing	42.1 elizied decreasing		5.3.4.4 all internally generated unbalies relevant broadely completed to date	2,7. The <u>theined Health Dispatanals</u> approach billies in the same of impacted impredicate of axial wright including context of an evel (fundre of wright and an firmation of TSE/DE fore which.)	Part III Pharmanelum and Insimilary study
reproduction toxinateding III A.C.M.3 developmental tox III R.C.M.3 genetoxicity III R.C.M.3 servicepentally	III 1.3 Resider soch förd av Had Part IV Pre-attainad Balininad Ivia Expert Report	22.5. Human paintening 22.6. Undersized kinkspiral offents 22.6.4. Carainopeninity	4.2.4 elinizat phormanelogy 4.2.2 Training shedire 4.3 Discretizations data		5:14:4 all internality generated antimizer or brand to noticity sample built to date 5:14:3 Statistically available Pharmaneut and a fair product approach in any supersplay. 5:4:4:3 Statistically internative continuant in activity and the activity any supersplay date of small sample	arizal origin industry sector a local construction of origin and configuration of TEC/DEC formulation 2.8. The Genetic Researces Directors of the Department of Agriculture amount be 2.9. The Genetic Researces and the formulation for imported type of the direct state of the sector of the 2.9. The Decal Mark M Director and solator for imported type of the direct state of the sector of the sect	Part III Pharmaneling and Incidency along III. A: Expect Report V Samuray Pharmaneling and Inciding III.41 Statement as pharmaneling
	W - Lorley Prevalisinal		1				
III R. Chi. J. akarepline afler lapital ane) III R. Chi. + Olkern requirements	IV.akapter Prevalizinat I regionarata IV.1.6 Phonosology	II.E.I. Frenchageneinille II.E.S. Halogrammie	4.4 Resistance statice 4.5 Efficacy staty could		5.2 Emailmenten I.I. Safelly, Judy required for final axiast products; eller products an regard enception from th 5.3.1 Profil Identify that relevant to contract the acting	interiorantij 1. Rom material openifications and under the provedurent	111. 13 Stady reports an aufoly phonocaling (General phonocaling) 111. 28 Stady reports an airceáistagicat arasiliaity
And the share of and all	Phorean-Interior	I.S.S. Realistance	4.5 Other information		5.2.4. ERA - Environmental Rick Americansi, if relevant furly retriant in fundational products)	(4) C. Room and series a specific actions, and numbers promodeness: 1, S. Specifications of another to a third or fractions which also activate the activation of activation with the activation of an application flacts and southed promoted are activations and the field streaming.	111. 24 Study opportung kormanklinetting
ainrakinlaginal propretire of craiting (homes got flore /	IT.LET.	and the second	4		5.4.1. EXH - Effective and a second		10. 21 304 99
recordinate legitimation III.6.(54.1.4.4) III.6.(54.1.4.4) III.6.(54.1.4.4) III.6.(54.1.6.4) IIII	IV.1.8.2 Pharmankineline IV.1.8.2.1 Dielingenikilityfkinegeissten	II.E.S. Plant Sycarconics II.E.S. Konceleniatis	4		5.2.2. All forther information related in anticip in the continent of	 Parques of each insuline (e.g. smalaifier). Medifiedine of insuline and allow was subsidiirerantalise of adother Coff in analisidian 	10.22 Shalq eeyacha aa aada haxialiy aayyiin 10.23 Shalq eeyacha aa aada shaxaala haxialiy (20-30 Aaya)
III B. Chil. 4. adarrena firm in kunzen kanteria ingurtant far kunze III B. Chil. 4. koatilik III B. Chil. 4. mer nafely	W.1.0 Foldspatiality for spin-layer W.1.0 Talescare is larged asiad W.1.0 Afrig W.1.0 Residence W.1.0 Residence Clinical requirements General principles H Condent vehicles to blate	11.5.5. Reserverillarite			5.2.2.4. «Watersalls scorrated abdies referant to corresponded a fets somebried to date		
III M. Chil. 4. aner safely	W.A.C Residence Clinical requirements	II.S.I. Hegorosomiliaile II.S.S. Rogendantine faminike			5.3.3.4. att internalig generated abulien extense to environmental notety completed budate 5.3.3.3.9 attributed literature extense to notety of the automaxis the environment.	5,4. Water Iralian proceedings and results where applicable. 4. Combainer and parkaging operationalisms:	10. 24 Study separts an antigeniaily 10. 25 Study separts an expendication (including beckgeniaily)
III A. Chil. 4. Eastaniaily	17.akaples Greendprinciples II Geoduct of alliand triate	II.6.5. Divelous sevent liters			S.3 Banan Fund Safely (mit reprired for find animal probabilit)	4.4. Part de la filia de la mandal de mandal de ser de la mandal de ser de la mandal de ser de la mandal de ser	111. 28 Stadų separta az akranis tasisitų fizatadinų asesiaugraisitų
		Brailers of artisinal scalaria					
Englas for VMP NOT assoliting GMO: 2 planes IT A. Chil. 4.1 VICH	IV.2.1 Clinical development plan	22.7. [ADI, HRL and withdrawal lines]			S.S.B. Deaff Labelling leaf coloured in homen fund mafely	4,2. Details of the manufastance of analyiness, etc. and he granided.	Special activity of invitability (basel, equivain and phaleses affine basis)ing brands; (0. 27 - Invitability)
		faeller					
Evaluation GHO (apprairie matrixing GHO (apprairie 10.4. Ch1.4.) calculation (SCI	Clinical briats final aling all 197.2.2 adversa finand Instance and decouver to	indiana.			5.3.4. Metabalise and evolute Kineline 5.3.4.4. ADME	4.1. Willing process of the immediate matchine with formulation [16 and demonstrated and examples] (4.1. Printle demonstrate in the control of the formulation patients for the following of the formula (4.1. Printle demonstrated in the control of the following of the followin	arian Paul IV Per aliainal balining briats
IIIA Chil: prescalation of partic	salars and dessurate	Conversity General presentions (Maray emailing of Conversity) General Maray Conversity Maray Maray Maray Maray Maray	/ **!		5.5.1.1. ADHE	 Delieft, deuerite auguster unstalarerfarmuslarg unstalare [atus delait un application form]. 	17 28 Esperi Report / Summary Per attained & attained Inists
		the product Impact of ferencing, head, light,					
		24. is pulled an aurekannen eta.)			5.3.4.2. Depletion of confidence 5.3.4.3. Residence and planet method funditudition	4.5. Provide details of primary and consultary produces, if relevant [also detail on application from 6.5. Institute all grands allows, [also details application force]. S. Homeford Institute grands drawn [Foundation for dispace].	n), 1923 Provalizing organization 19258 Proceedings 19 Proceedings in the pertained
IIID Braidar Irala		o. Sainalifia papera and/ar managrapha	1		2	5. Haufastering provideren [instaling finn diagram]	IV Pharmandynamias in larget animal
		* Saivalifia poposa andfar marage aph Translaline of annuary and analysisan inofficial saymary Spanisk, 28. Parlayang Salaky,	4				
					5.3.2. All fuelles information related to known fund safely	5.4. Hourf adapting facility for and physical address for finduling partners).	19 2362 – Pharmanshinelinn in larget animat 19
abl Professerer of Irala		27. Additional information 28. Adherical signal see			5.3.3.4 all interesting second of shafing out reads to soft by its hours find a single to be taken 5.3.3.5 all interesting and the solar on shafing and the solars is fitness out a share shafe. 5.4.5 and 5.4.5 and 5.5 and	forminal analysis provider ends. 5.2. The filling process of the investigle multimer and he densetted in detail.	2763 Distinguishiling/biorgainsteare 19239 Talesane in largel united safety with 42, 52 and 52 of second raded damage (Dai
1110 al. Performance of hele al. Performance of hele Dissection of the second Dissection of the second 110 August and the second 110 August and the second 110 August and the second 111 August and the se					5.4. Howe Commune Safely 5.4.1. Here Rick Research. Panel analytics and to published like share append suprane to human mere as Efficiency.	 Restauration is satisfying and plants of starter in a plant starter in a starter in	W Performaniki/Warefulner W100 Construction of an and straining with the straining
HID CAIL: prevalation of parti-	indare and descerate Initials					 A many starting provident transformation of the interpretation of the inter	ni, en 19 December Strand and Strand Strand 19 Canada of Invalue Strand Strand Strand
IT Chi Per-alisiaal IT Pharmanelage	1				El Sori I debinistra interest formantes El Sori I debinistra interest formantes El Sori Antonio antonio debinistra del Soria Antonio del Soria	 Consisting defails of final/finished product [holds or boar decourdabling much by provided E.S. Confiftuate of analysis [at treat 2 holds of an anaparg following, dated and holds or board on the second seco	97 Candida Bard Anna Anna Anna 2014 - Paril Residan Anna Anna Residan 7.32 Felalina atomia Kintin 7.33 Felalina atomia Kintin 7.33 Felalina atomia
IV Pharman departies					E.A.A. Daar ak contrination (daar fidning abatim or supported by filorators) E.A.Z. Daar anafirmation (applicable for paramitinide analy, 2 abatim required preparamite stain) (2011)	2. Statility data (2 - 9 katakaa):	V.32 Heldeline and residen Kineline V.33 PK (ADHE)
IT Chill Clinical experience	and aprairs				E.3.4. All internality retracts the offentioners. E.3.4. All internality proceeded dudies retract the offention of the advance for the interded are.		V.35 Depiction study of considers T.35 Resider and bind without and without sufficients
Chi.e. Physicalization (ADHE) IV Televant in Langel and IV Chill Chicken in Langel and IV Chill Description (In IV Chill Description) IV Chill Description (In IV Chill Description)					E.J.2. Published life after referant to officiary of the address for the intended one.	 Stability along probability in the second second stability and include providers to the second second stability in the second second stability and full the second second	7.87 Willioud print of scholaline artiked Pool 71 Exclosuring Hy propert skylif life (for arterinary kialogicals like skylif life will k
IT Chi fortistatore						a. Constantine - the most contact the uniteration and anticonter of the	ir prepard shelf live (bar arterizery histogiczis (br saver over som s
						3. Pharmaneolinal development	
						 Providinizal data (no position advance) Photometry in differentiate (advance) Photometry and the industry of the indust	
						1, all, Pharmannian of antine ingertical	
						1999, Phone confidentiate of colling in collecting barrel opening, accions control of administra 1995, Pane determination triated Perel biolet History History of Feature States and States and States and State	salian Ing Far angkin diana
						1,6] Hannalias Insisily abdies: 1,4] Eastenmental Statics and Rick Assessments	
						C. SAFETT DATA Riskle of analysis for His analysis and to invested.	
						C. SEFETY PATA Ridde Sensitive for History and the intercled. D. EFFICECT PATA Ridde Sensitive for History and the intercled Ridde Sensitive for King and the sense of the intercled in the termining of the for all difficult distances in table for the and and the needed life in the the of the sense of the sense of the sense of the sense of the sense for all difficult distances in the sense of t	
						An official data bial annuary in labelse formal and to incode dia the terminant of the Fore all allocing the labor to be also be also been and the antual for the labor	
						brokingers for authotalating, endentagides and	
						E. RESIDNES E. (State of controls for this world in much to inserted. E. ? control to find musicary in taketor formal much to inserted in the trajenting of the oralize.	
						E.2 consider local numbers in labolar formal and by increded in the beginning of the oralise.	
						The Automatic State of the Second Level INCENT IN Planner Effert Level	
						C. S description Definition (ADD) and the Different Lowel (ROCLE) NonReserve Different Lowel C. S Description (Billion and a provide for constant approximate (Richel Bieserschaft Karreges, C. S Description (Billion and Berlander) C. S Description (Billion and Berlander) C. S Description (Billion and Berlander) C. S. Description (Berlander)	

Funded by UK Government

WORLD ORGANISATION FOR ANIMAL HEALTH Protecting animals, preserving our future

Starting point: Analyzing current veterinary dossier structures

- HealthforAnimals compared dossier structures for pharmaceutical VMP in **8 geographies**:
 - Camevet, China, EAEU, EU, Japan, South Africa, UEMOA, USA

Conclusion

- No more "international summary dossiers"
- Content mostly the same
- Order and naming conventions differ
- Level of detail sometimes different
- Confusing for many "third country" authorities





Vision, in a nutshell...

Guideline at VICH level

• Products in scope as defined in local legislation

Global Dossier Framework:

- A modular skeleton
- Standard location for data sections
- Authorities decide locally/regionally on granularity and level of detail



Potential issues, working towards a vet GRDF

- Creep of requirements
- Requirements **above legal** requirements
- **Resources** (VICH EWG) to be invested by all stakeholders to create a VICH GRDF
- Geographies will need to **adapt legislation** to the new structure
- Authorities "grabbing" opportunity
 - to reopen approved dossiers asking standard reformatting of whole dossier
 - to ask reformatting of all dossier for (minor) variation(s) in one part
- Upgrade will also be needed for API manufacturers (**closed ASMF**)
- Scope limited to **VICH regulated** products : regional exceptions!
- In transition period, need for **correlation tables** between old and new format





Benefits/opportunities of a vet GRDF...

- In line with **trend** not to accept international summary dossiers
- Get **rid of current confusion** @ reg agencies globally, created by different structures from Japan, US and EU
 - While content is essentially the same, order and granularity can differ
- Skeleton approach
 - allows regions/countries to ask for the granularity required by law
 - allows not requiring some sections (if not in legal requirements)



More benefits/opportunities of a vet GRDF...

Global standard

- Stimulus for global **convergence** and harmonisation
- Increased probability of entry in more markets
 - GRDF enables truly global development plans
 - parallel or joint assessments are empowered by GRDF
 - mutual recognition is strongly facilitated by GRDF
- These last two points result in less resources and time required to bring vet products faster and to more places where they are needed
- Common global framework simplifies building of electronic pdf files, and therefore paperless submissions





In conclusion: the vision, short-mid-term

- Short- to mid-term a VICH modular skeleton for dossier content
 - Chapters on admin info, chemistry-manufacturing, pharmacology and safety, efficacy info and an "additional info" section for "local data"
 - High-level modules, with a level of granularity as required by local law
 - Some modules, like chemistry-manufacturing, can be close to human CTD to allow re-use of human dossier or active substance master file
 - Allowing easier development of e-submission platforms





In conclusion: our vision, long-term

- Long-term: a single veterinary dossier, acceptable everywhere
 - VICH facilitates further future convergence of dossier content
 - More need for same or similar dossiers, responding to increased recognitions and joint/parallel reviews
 - Long-term, a single submission of a dossier in a common filing system, allowing countries and regions to recognize approved dossiers easily



