

Lhasa Limited

is a developer of expert knowledge based prediction software and chemical databases.

vitic[®]
excipients

2012 Virtual ICGM series

Joanna Edwards

Senior Scientist, Database

lhasa
limited

Tel: +44 (0)113 394 6020
Email: info@lhasalimited.org
Web: www.lhasalimited.org

© 2012 Lhasa Limited Registered Office: 22-23 Blenheim Terrace,
Woodhouse Lane, Leeds, LS2 9HD, UK Registered Charity (290866)



- ④ What is the Excipients project?
- ④ Joining the project and data donation
- ④ Current database



What is the Excipients project?

- An initiative involving the reciprocal sharing of vehicle toxicity data from single and repeat dose studies
- Originated from the Dog Project:
 - Ten pharmaceutical companies plus charities (RSPCA and FRAME) with a shared aim to reduce the amount of animal testing carried out
- A wealth of vehicle toxicity data is held in archives. Incorporating this into a database would mean less repetition of experiments within companies
- Sharing the data could reduce the number of vehicle control studies carried out by other organisations.



The role of Lhasa Limited

- ④ We were approached to host the database and facilitate data sharing and data entry as we had prior experience in several data sharing projects
- ④ We are the trusted intermediary and treat the data with the strictest confidence
- ④ We not only develop and build the database, but we carry out all data entry and peer review ourselves
 - ④ We are well placed to deal with any queries on the database or the data within it.



The Excipients project

- Anyone who is able to donate their own vehicle toxicity data can join the project
- Members donate 50-60 records a year for the first 3 years
 - Data donation is scaled according to company size
 - Membership fee is scaled according to company size
 - Data donation requirements may be lower if you donate certain types of data (in areas deemed important by the steering group)
 - Data donation is anonymous.
- Project is now in the maintenance phase
 - Some members have exhausted their archives and are now donating data from recently carried out studies
- New members joining will begin a 3 year project phase.



Data Donation

Study No:	
Study Duration:	Study Type:
Species:	Route of Admin:
Strain:	Age at Start:
No. Males/Females/Both:	Dosing Regime:
Dose Volume (mL/kg):	Infusion Time/Rate:
Vehicle:	
Clinical Signs Performed? Y/N	Bodyweights measured? Y/N
Food Intakes measured? Y/N	Water Intakes measured? Y/N
Haematology measured? Y/N	Clinical Chemistry measured? Y/N
Urinalysis? Y/N	Ophthalmoscopy performed? Y/N
ECGs measured? Y/N	Macropathology Examination? Y/N
Organs Weighed? Y/N	Histopathology Examination? Y/N
Other parameters measured? Y/N	
TK of Vehicle Components:	
Vehicle Toxicity:	
Tolerability (Delete as appropriate): Not Tolerated / Tolerated with Findings / Tolerated with no Findings / Inconclusive	



Data Donation

- ④ This format is the most common used by current members
- ④ Ensures that all necessary information for a complete database record is included in the data you send
- ④ Also ensures that no proprietary information is sent to Lhasa Limited
 - Easier to get approval from legal department.



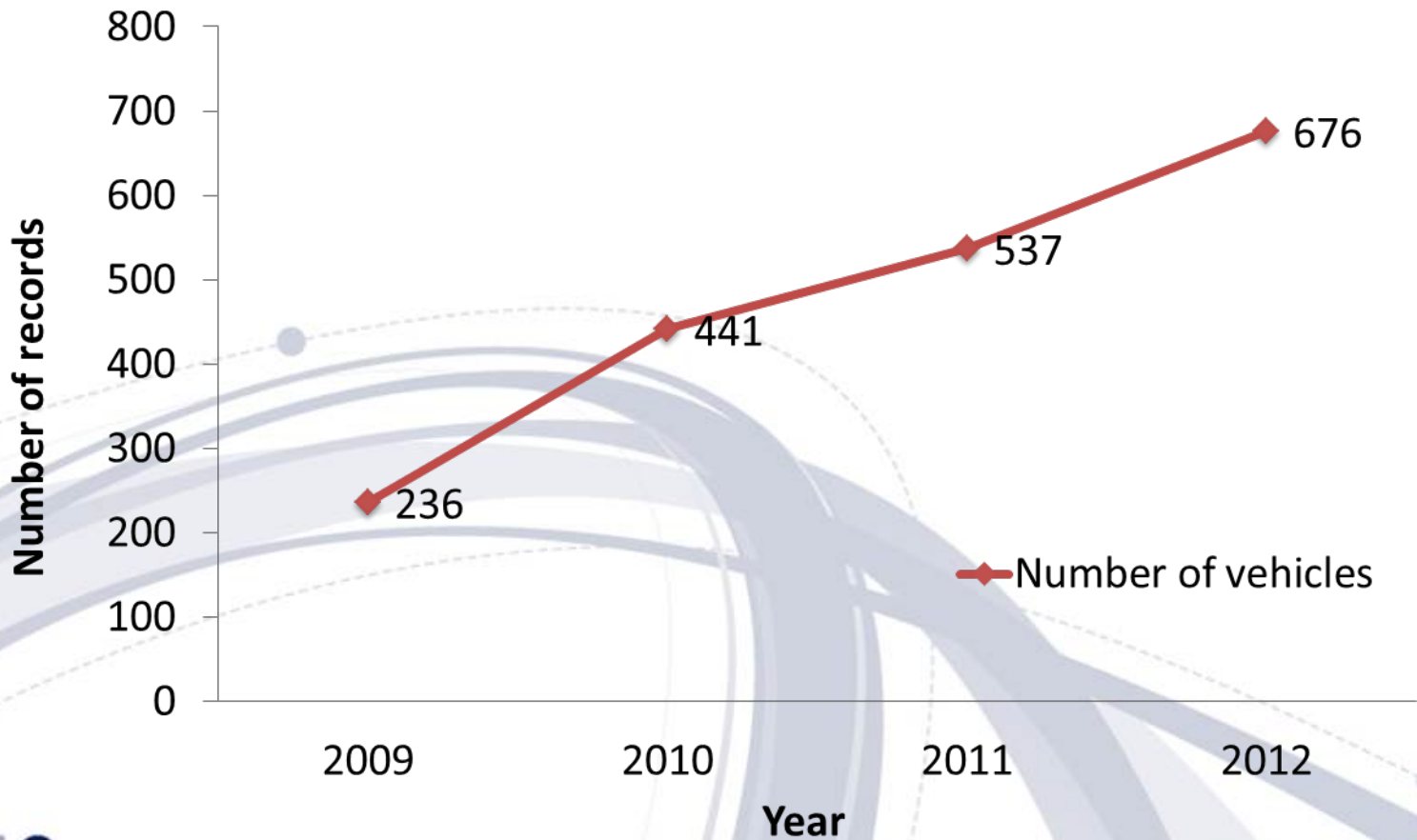
Data Donation

- We will accept data in several formats
 - Excel spreadsheets
 - Study reports
 - Database files
- Lhasa Limited may be able to assist with the data extraction process.



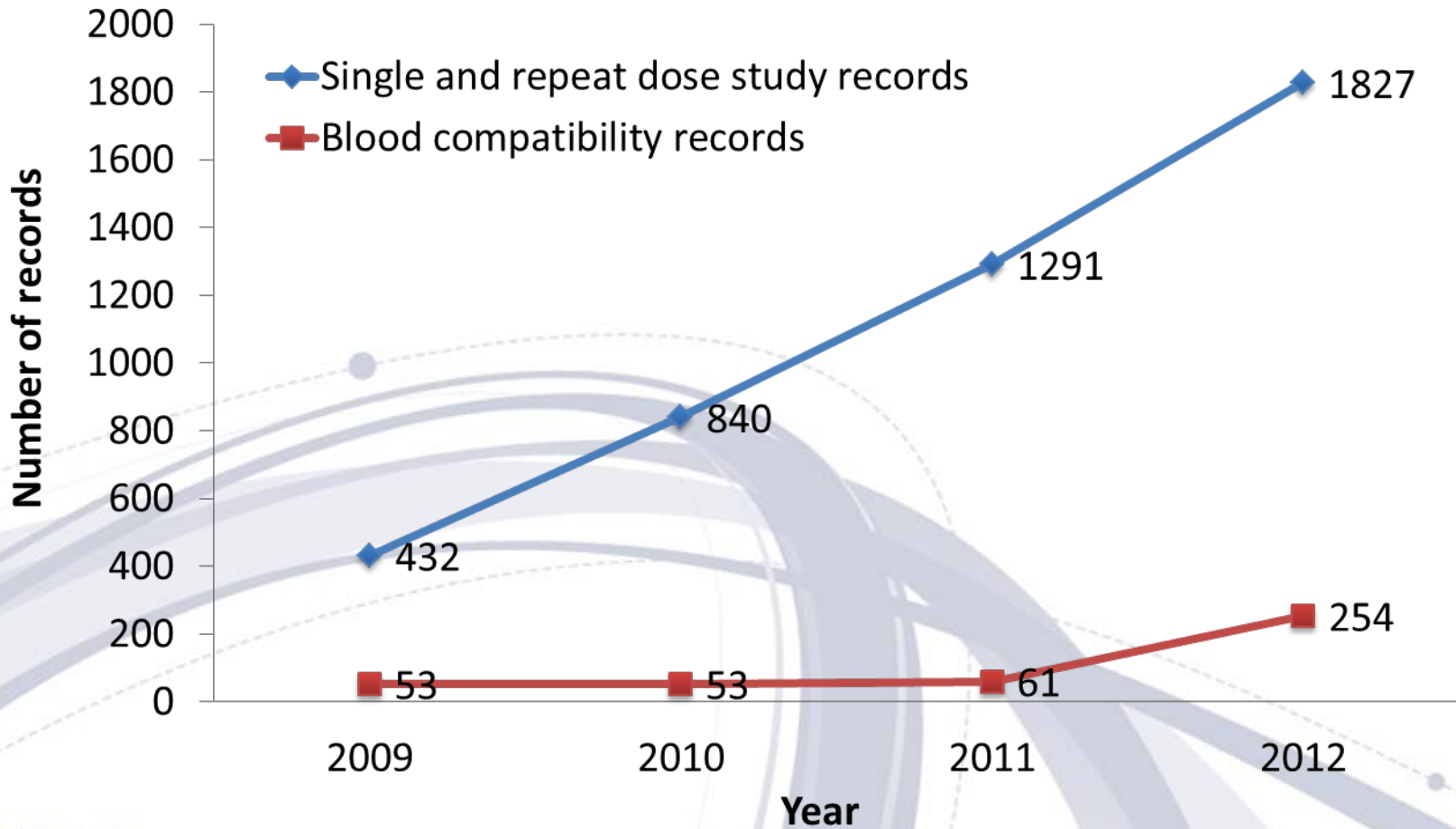
Database Growth

Cumulative Number of Vehicle Records



Database Growth

Cumulative Number of Study Records



Database Content

Species	No. of Vehicles	No. of records
Dog	196	321
Guinea Pig	29	66
Minipig	28	32
Monkey	81	135
Mouse	72	135
Primate	6	11
Rabbit	76	112
Rat	420	1015



Database Content

Route of Admin.	No. of Vehicles	No. of records
Dermal	21	31
Intraarterial	3	3
Intramuscular	3	3
Intranasal	1	4
Intraperitoneal	22	29
Intravenous (bolus)	135	255
Intravenous (infusion)	81	189
Intravenous (unspecified)	33	55
Occular	1	1
Oral (gavage)	370	1050
Oral (dietary admixture)	3	17
Oral (unspecified)	54	125
Oral (capsule)	7	7
Perivenous	3	3
Subcutaneous	35	53



Database Content

Length of study	No. of Vehicles	No. of records
1 day (single dose)	260	583
2 – 7 days	163	251
8 – 14 days	207	369
15 – 31 days	214	395
32 – 93 days	79	150
94 – 273 days	34	43
≥ 274 days	9	21



Database Content

Tolerability	No. of Vehicles	No. of records
Tolerated without findings	475	1385
Tolerated with findings	171	325
Not tolerated	51	66
Inconclusive	48	51



Database Content

Record type	No. of Vehicles	No. of records
Carcinogenicity	3	9
Juvenile Toxicity	4	5
Reproductive Toxicity	69	154
General Toxicity	525	1523
Blood Compatibility	60	254
Genotoxicity In-vivo	6	6



Database Content

- Literature data

- Also include published data where appropriate
- Project members can request we include certain literature references

- One point of reference for all your Excipients queries.



Lhasa Limited

is a developer of expert knowledge based prediction software and chemical databases.

For further information please contact marketing@lhasalimited.org



Tel: +44 (0)113 394 6020

Email: info@lhasalimited.org

Web: www.lhasalimited.org

© 2012 Lhasa Limited Registered Office: 22-23 Blenheim Terrace,
Woodhouse Lane, Leeds, LS2 9HD, UK Registered Charity (290866)

