

FIGSHARE

AT DE MONTFORT UNIVERSITY

Geoff Smith
Prof. of Pharmaceutical Process Analytical Technology

March 7th 2019 at the University of Leicester

RESEARCH



The Projects

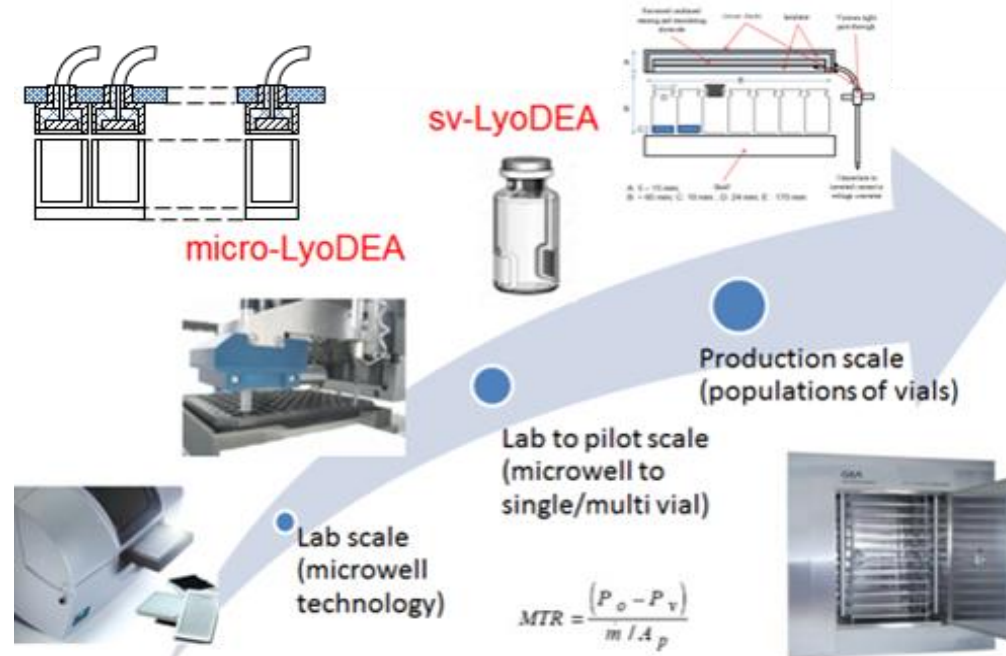
LyoDEA

Lyophilization process analytics
By dielectric analysis



The Vision

Scalable Process Analytical Technologies



Process characterization for scale up

Product Temperature + Drying Rates → Kv and Rp



The Projects

LyoDEA

Lyophilization process analytics
By dielectric analysis



The Product "Range"

TVIS-C



TVIS-NC



Through Vial
Impedance
Spectroscopy

TVIS-Hydra



Z-FDM



Innovate UK

Government Support for industry

The Projects

LyoDEA

Lyophilization process analytics
By dielectric analysis



Biopharmaceutical Stability at
Room Temperature

AtlasBio 

Analytical Technologies for the
Stabilization of Biopharmaceuticals



EXTALcoat

Process Design Excellence
for External Tablet Lubrication Coating



The Partners



UK Gov Standards Agency, Catapult Centres, HEIs



engineering for

Process Engineering



is-instruments



Instrumentation



scientific instruments



powder characterisation



Contract Research

biopharma process systems

SANOFI

Large pharma

AstraZeneca



nutra^{pharma}
health by stealth™

Innovative SMEs

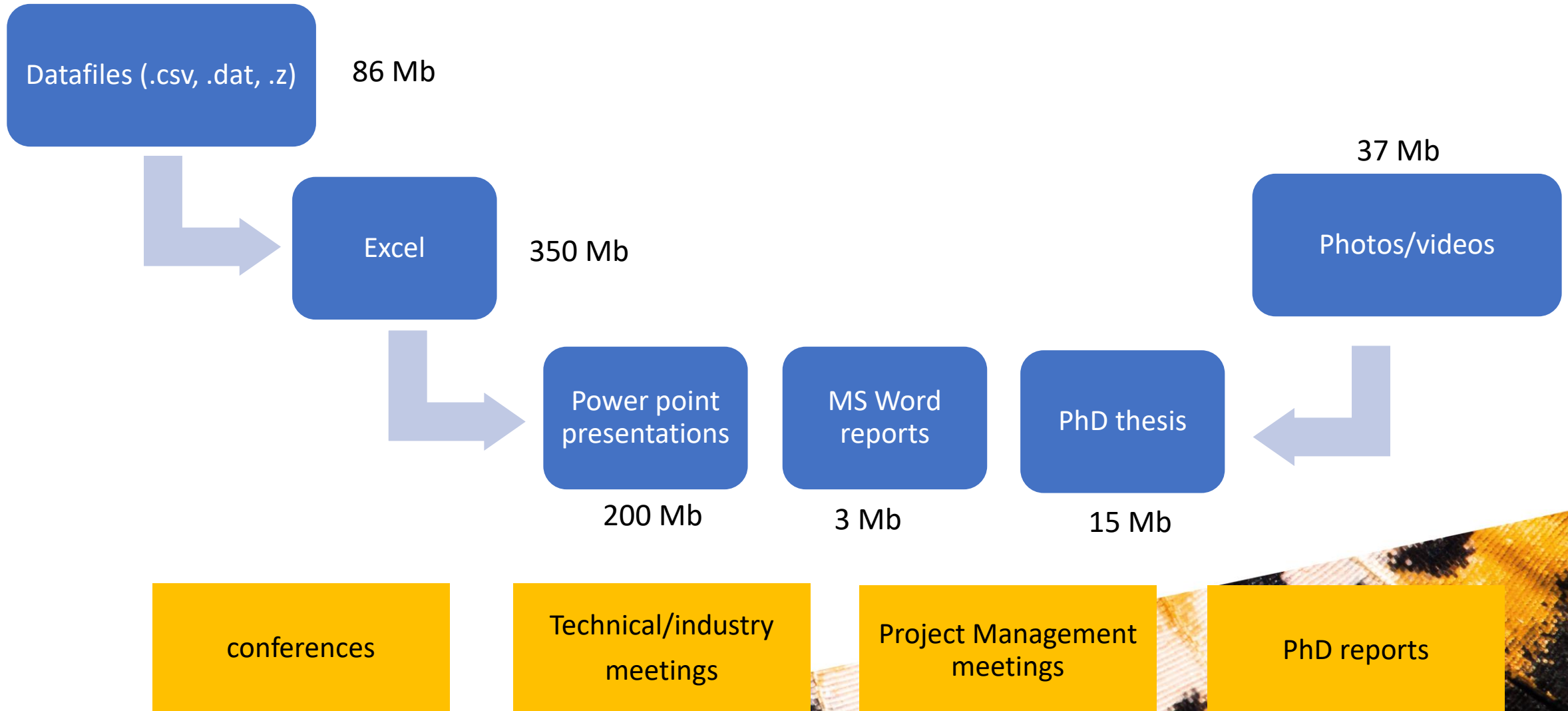


MICRON DESIGN
Complete Engineering Solutions

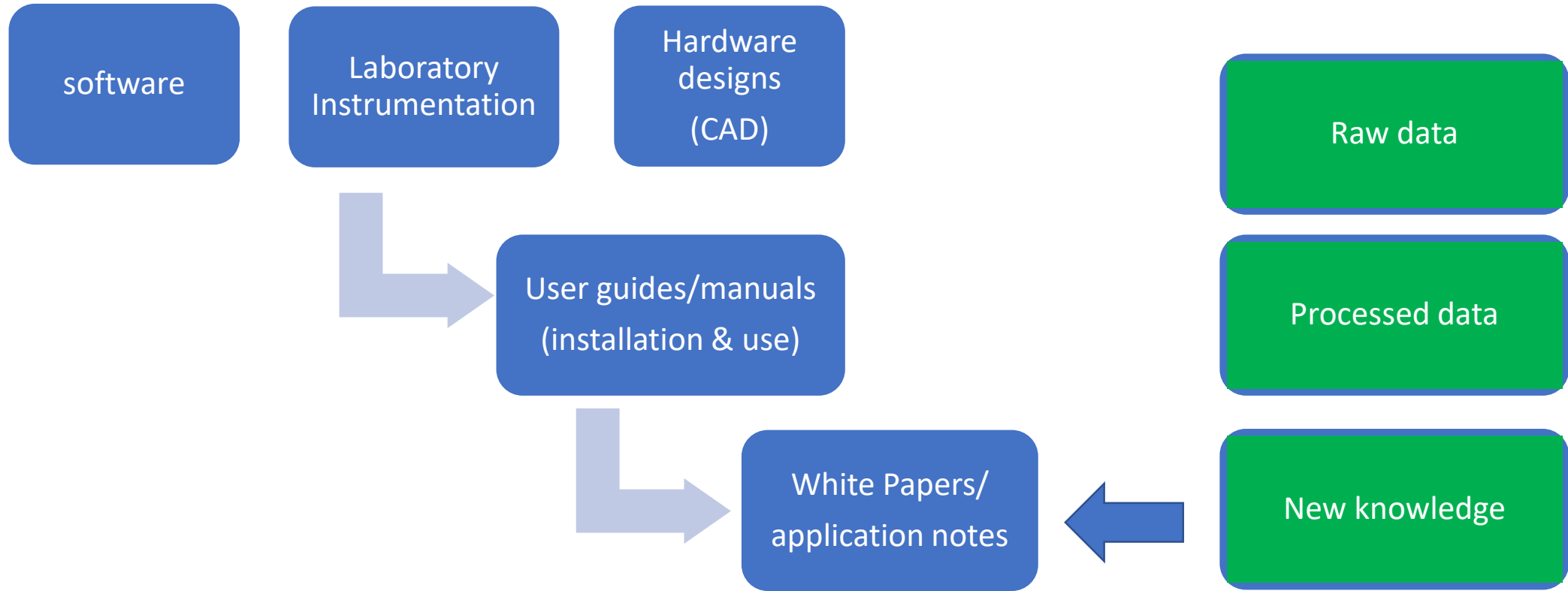
Engineering and Product Design



Laboratory Research



New Product Development



Supply chain

Co-developers

End users/evaluators

DMU IP/legal services

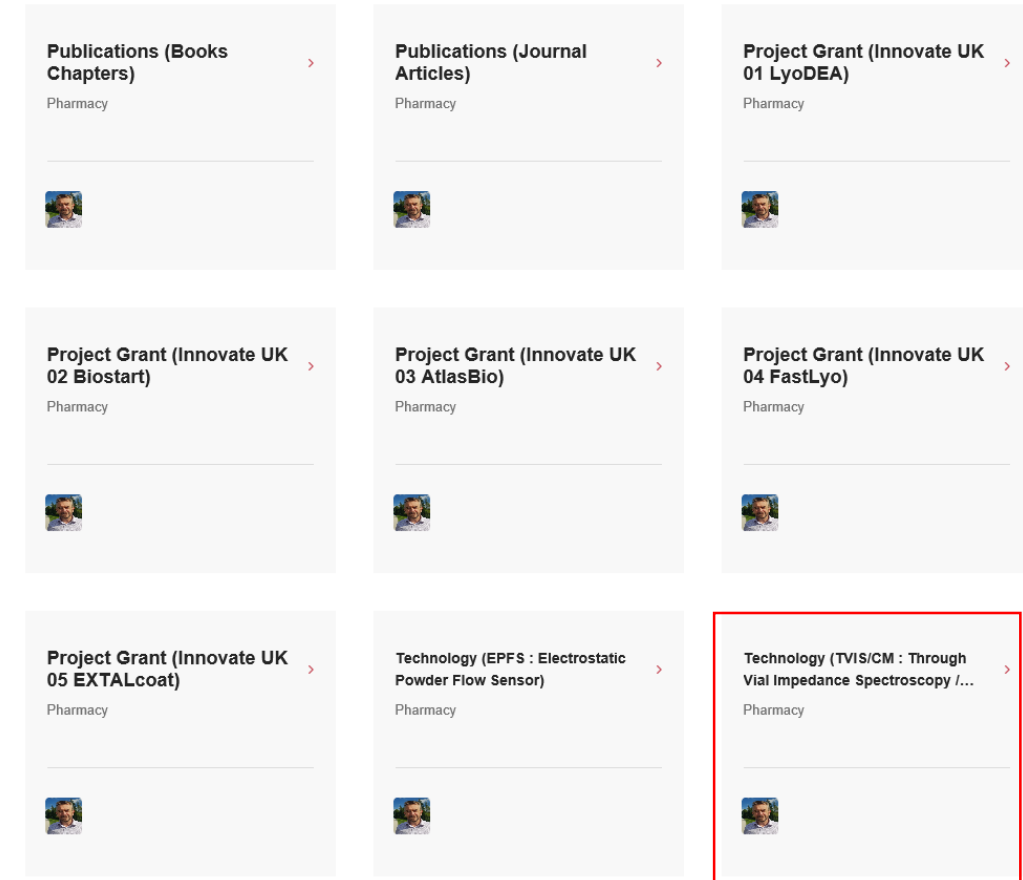
Organization using Projects

DMU Process Analytical Technologies

- I have three impedance technologies (TVIS, Z-FDM, Z-HTFS), one electrostatic powder flow technology (EPFS), and a number of laser based technologies (Laser Speckle, Quantum Eraser, Laser Absorption in freeze-drying).
- For each we have user guides for the equipment and how to process the results; and where there are no PhD students working on these (e.g. Ahmet's laser technologies) we'd also have presentations and reports on the data we gather with these laser technologies.

One Project Folder for each of the technologies being developed by DMU.

- **TVIS (Through Vial Impedance Spectroscopy)**
 - This technology has been developed through various Innovate UK collaborative R&D projects and has led to the creation of a number of instruments
 - Each instrument Type should have its own **fileset** containing the SOP (in Word) for installation and testing of the system. There may be more than one SOP for each instrument with each pertaining to a different freeze-dryer in which it is installed.
 - DMU 5 channel TVIS system
 - Sciospec ISX5 TVIS system
 - Sciospec 5 channel TVIS system
 - DMU single channel non-contact system
 - There are also common components used in each system, such as cables, connectors, pass-through elements that could be stored and given open access so that our tests site adopter can access the relevant details for spare parts and systems development purposes
- **FDZM or iZFDM (Integrated Impedance Spectroscopy and Freeze-Drying Microscopy)**
- **Z-HTFS (Impedance enabled high through put formulation screening)**
- **EPFS (Electrostatic Powder Flow Sensor)**
- **ILSI (Intelligent Laser Speckle Imaging)**
- **LyoLAS (Lyophilization Laser Absorption Spectroscopy)**
- **QMT (Quantum Measurement Technologies)**



External Collaborations

Project Collaboration (TVIS Installation at Chulalongkorn University, Bangkok, Thailand)

This Project Collaboration has FIVE Filesets:

01 Project Funding

Internal or external grant applications, inc. travel grants

02 Legal

Collaboration agreement (CA)

Non-disclosure Agreement (NDA)

Material Transfer agreements (MTA)

03 Standard Operating Procedures (SOP)

SOP for hardware and software installation

SOP for the use of the instrument

SOP for data processing protocols

Excel templates for data presentation and analysis

04 Validation Tests and Calibration Data

(subject to company policy)

Each data file should be named according :

VAL001_YYYY/MM/DD_short description

05 Experimental Data (subject to company policy)

Each data file should be named according :

EXP001_YYYY/MM/DD_short description

06 Promotion and dissemination

Photographs of site visits

Emails authorising use of photos



One Project for each PhD student (Privileges: student and supervisors - RW)

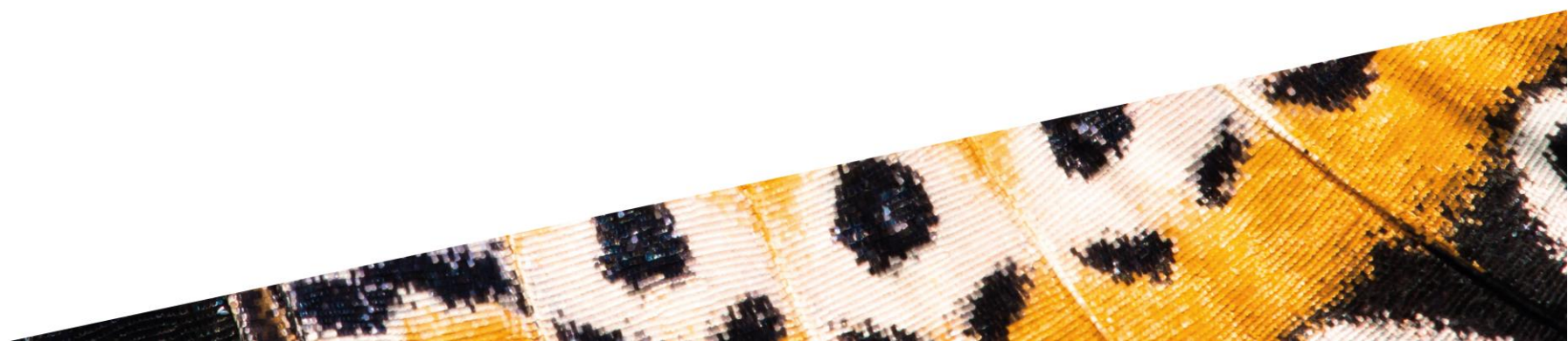
Filesets for :

- Student Profile and Project Summary
- DMU documentation
 - Registration document (Word)
 - Annual Reviews (One PowerPoint report for each annual review (with the annual review date on the first slide))
 - Formal Review (MPhil /PhD transfer): Report (Word); Report (Power Point)
- Experimental
 - To be organised into sub folders (one per experiment)
 - Format for the title of the folder : 2019-02-01 short title
 - Example : 2019-02-01 TVIS study of the freeze-drying of sucrose/NaCl solutions
 - Each experimental **fileset** should include:
 - a copy of the experimental protocol (in power point with images of the experimental set up)
 - raw data files and images
 - processed data (e.g. Excel Workbook with data and figures)
 - There should be links to the copies of any SOP for the experiment and/or data processing routines (located elsewhere on Figshare)
- Reports
 - Literature Reviews (Report in Word to form the basis of the introductions to your formal review, your annual review and your thesis)
 - Interim reports, e.g. Power point presentations and Word documents (do not include your annual review or formal review documents here)
- Publications and Conference Presentations (to be in Projects folders for conferences and publications)
 - One fileset for each conference presentation
 - One fileset for each publication
- Thesis
 - Word document

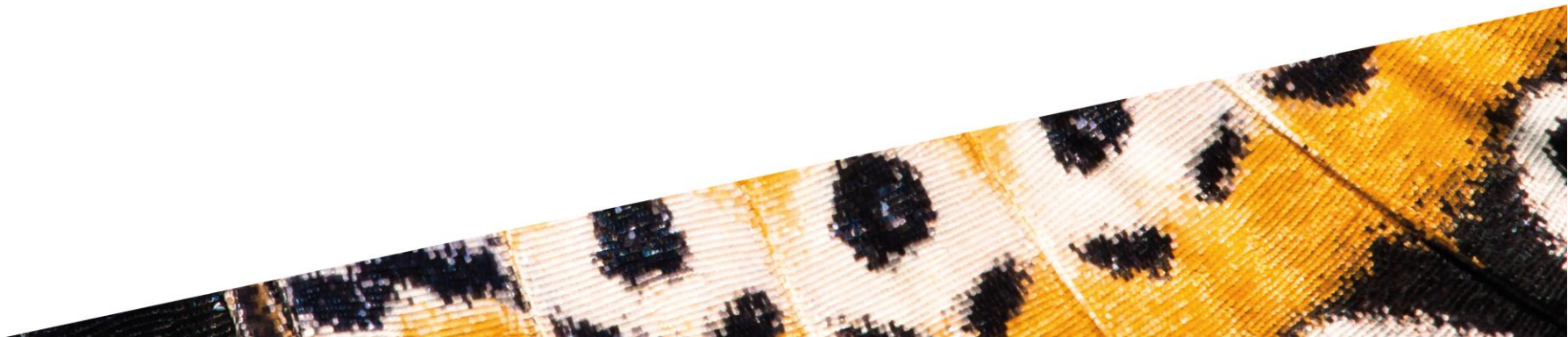
Externally Funded Collaborative R&D Projects

One for each of the collaborative R&D projects being funded by external parties

- These projects have their own set of documents, which can be separated into
 - pre-start documentation,
 - the grant application and annexes; the supporting documents such as the collaboration agreement, financial plan
 - post-start documentation,
 - quarterly progress reports (folders named Q1 Report, Q2 Report etc., each containing the minutes of meetings and the quarterly progress report – usually a power point presentation) etc.
- **LyoDEA**
- **Biostart**
- **AtlasBio**
- **EXTALcoat**
- **FASTIyo**



Examples to date



Conference presentation

Generate private link

<https://dmu.figshare.com/s/b279b67ab421a5e5e8ea>



Impedance Spectroscopy :
Recent Developments as a Process Analytical
Technology for Pharmaceutical Freeze-Drying



Prof. Geoff Smith

Leicester School of Pharmacy, De Montfort University, United Kingdom



Product Design



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Search on De Montfort University...



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← Project Grant (Innovate UK 04 FastLyo)

487.09 kB  10 GB | MANAGE 
request more storage

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Sort ⌵

Filter ⌵

search items



20.2.2019
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Micron Design



FILESET

