TRISTAN WP2 Phantom quality control image acquisition manual for gadoxetate MR imaging for drug induced liver disease

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AUTHOR	Bioxydyn

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1 TERMS, ACRONYMS & ABOUT THIS MANUAL

1.1 Terms and Acronyms

Term / Acronym	Definition
DCE-MRI	Dynamic contrast-enhanced magnetic resonance imaging
DILI	Drug-induced liver injury
FOV	Field of View
GRE	Gradient Echo – this term is used as a generic term to describe the RF-spoiled spoiled gradient echo (SPGR) sequence across vendors, i.e. FLASH (Siemens), SPGR (GE) and T1-FFE (Philips)
IAF	Image Acquisition Form
RF	Radio frequency
T	tesla, e.g. 3.0 T MRI scanner
T_1	Longitudinal relaxation time
T_2	Transverse relaxation time
TRISTAN	IMI2 project Translational Imaging Methods in Drug Safety Assessment Grant Agreement no.: 116106 IMI2 Call topic identifier: H2020-JTI-IMI2-2015-06
WP2	Work package 2 of the TRISTAN project

1.2 About this Phantom Imaging Manual

This Phantom Imaging Manual has been created by Bioxydyn for use in the TRISTAN WP2 studies concerned with drug-induced liver injury (DILI). Study subjects may be healthy volunteers or patient volunteers, or a combination of both. This Imaging Manual's intended use is by the MR radiographers/technologists/personnel, who have been trained in the phantom scanning procedures described herein. In the event that a trained study individual cannot conduct a phantom scan, Bioxydyn should be informed immediately (see section (§) 6). The trained study individual may use this Phantom Imaging Manual to train other individuals in the scanning procedures.

Bioxydyn control the versioning of this Phantom Imaging Manual. If a new version is released during the study, please destroy the previous version.

Throughout this Phantom Imaging Manual, the following action characters are used:

> A red angle bracket symbol is used to define a procedural action

> A green angle bracket symbol and green text is used to define an action related to completion of the Image Acquisition Form (IAF - Appendix)

2 GENERAL IMAGING REQUIREMENTS

2.1 Imaging phantoms in TRISTAN WP2 studies

The phantom for use in TRISTAN WP2 projects will be the *Quantitative MRI (qMRI) ISMRM System Phantom (Model 130)*, available from the High Precision Devices[1]. The qMRI phantom was designed as part of a joint effort between the International Society for Magnetic Resonance in Medicine (ISMRM) and the US National Institute of Standards and Technology (NIST)[2]. This phantom will be used for T_1 relaxation time assessment (figure 1 and 2).

2.2 MRI Hardware, Upgrades and Maintenance

2.2.1 MRI Scanner

For longitudinal studies, the same scanner should be used for each scan visit of each subject, although different subjects may be scanned on different scanners/facilities. **It is important that the phantom is scanned using the same scanners that are used to scan subjects on the study.**

2.2.2 MRI Coils

The preferred coil has been determined during the study set up. **The same coil that is used to scan subjects must be used to scan the qMRI phantom.**

2.2.3 Upgrades and Maintenance

Any hardware or software upgrades or scanner maintenance must be communicated to Bioxydyn immediately (see §6). The site must not scan subjects or phantoms on an alternative scanner during any upgrade.

In the event of an upgrade, a phantom scan must be performed immediately and images submitted to Bioxydyn for evaluation. The site must not scan subjects until Bioxydyn has verified that the phantom data is acceptable.

[1] www.hpd-online.com/system-phantom.php
[2] http://collaborate.nist.gov/mriphantoms/bin/view/MriPhantoms/MRISystemPhantom

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3 IMAGE ACQUISITON

3.1 qMRI Phantom

The qMRI phantom is sourced from High Precision Devices (www.hpd-online.com/system-phantom.php). The phantom consists of multiple spheres (20 mm inner diameter) placed in arrays within an outer sphere (201 mm diameter) (figure 1). The imaging phantom should be stored safely to avoid breakage at all times when not in use.

> Store the qMRI phantom in the MRI scanner room for at least 8 hours before scanning so that it can equilibrate to room temperature.

Please contact Bioxydyn if you experience any problems with the phantom as these problems could affect analysis.

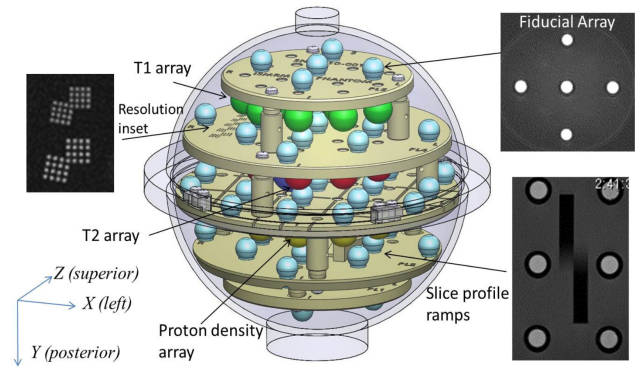

Figure 1: Cutaway and inner views of the qMRI phantom[3].

The qMRI phantom contains 14 spheres that cover a wide range of T_1 values (figure 2), in addition to 14 spheres with a range of T_2 values and 14 spheres with a range of proton densities.

[3] http://collaborate.nist.gov/mriphantoms/bin/view/MriPhantoms/WebHome

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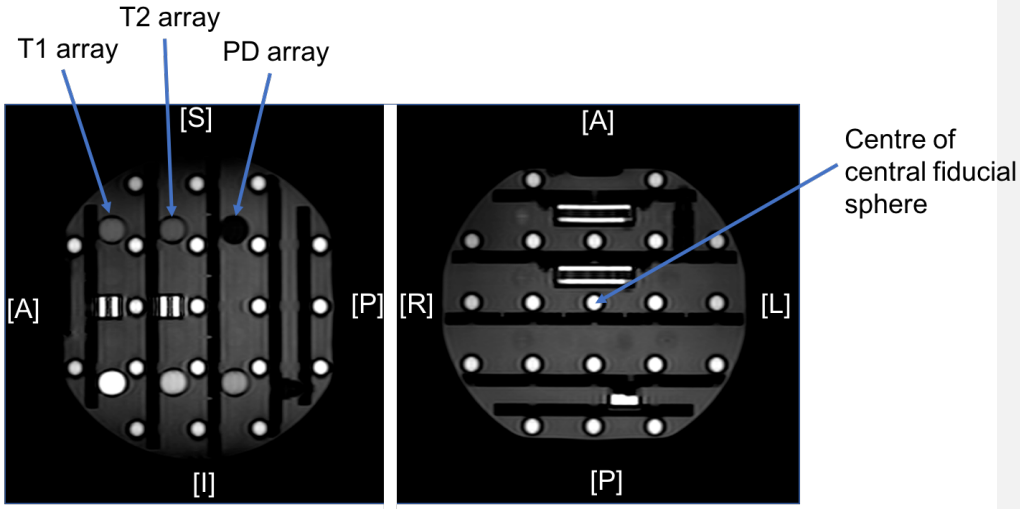

Figure 2: MRI scans of the qMRI phantom showing positions of T_1 spheres and other features.

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3.2 Phantom Image Acquisition

> Prior to each phantom scan, record the operator, date of scan, reason for phantom scan and **room temperature** on the phantom IAF.

NOTE: The thermometer provided with the phantom has magnetic components; measure the phantom temperature outside the scanner room after equilibrating temperature for a minimum of 8 hours within scanner room.

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3.2.1 Frequency of phantom scanning

The phantom scan should be run **every 6 weeks** for the duration of each study unless otherwise agreed. *Bioxydyn will inform the imaging site of the expected phantom scanning schedule for each study.* Bioxydyn may also request phantom scans at other times, and in the event of MRI scanner hardware and/or software updates (see below).

3.2.2 Reasons for phantom scanning

The qMRI phantom must be run routinely every 6 weeks for the duration of the study unless otherwise agreed. This is considered as on-going, or scheduled, QA designed to assess differences between scanners and scanner stability over time. This information will be used to identify if there are problems with scanners, operator performance, or acquisition protocols. It may also be used for calibration purposes during analysis of quantitative MRI readouts.

If your MRI scanner has a software upgrade, please scan the qMRI phantom immediately after the upgrade and send us the images to evaluate. Study subjects must not be scanned until Bioxydyn have verified this post-upgrade phantom data.

If your MRI scanner receives hardware upgrades or repair, e.g. gradients, coils, please scan the qMRI phantom immediately after the upgrade/repair and send us the images to evaluate. Study subjects must not be scanned until Bioxydyn have verified this post-upgrade/repair phantom data.

3.2.3 Imaging sequence overview

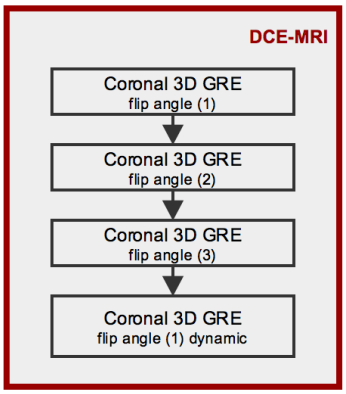

Figure 3: The DCE-MRI sequences to be run when using the T_1 phantom.

3.2.4 Phantom positioning

Ensure that you only use the coil **approved for your site and the study in question**.

3.2.4.1 Phantom positioning in abdominal/cardiac phased array coil

> The qMRI phantom should be orientated such that the inserted custom level faces the inferior end of the scanner bed. The air bubble within the level should be centered to ensure that the T1 array is perfectly horizontal. Use sandbags or foam wedges to position the phantom. This is to ensure longitudinal consistency of phantom positioning.

> Fix the coil onto the scanner bed ensuring that the connector is as straightened out as possible. Use sandbags or pillows to prop up the coil if it is unstable over the phantom.

> **Ensure offset = 0 and recheck air bubble position in the level.**

> Move the coil with secured phantom to the centre of the scanner bore (figure 4).

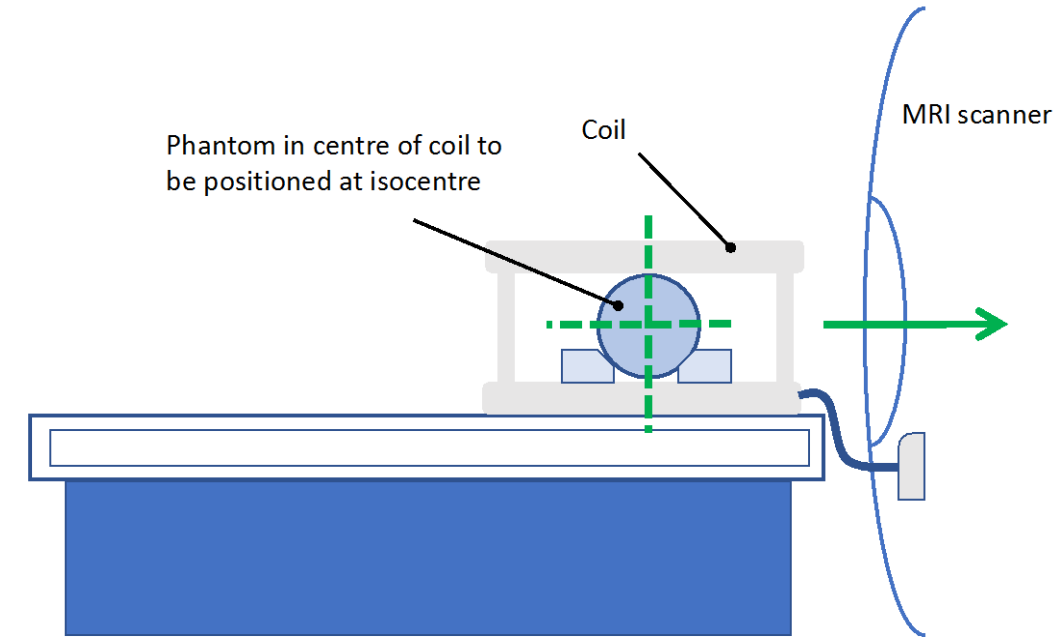

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Figure 4: The qMRI phantom positioning in the coil.

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3.2.5 Planning sequences for the qMRI phantom

Only the DCE-MRI sequences (see figure 3) should be run on the qMRI phantom.

> Run a 3-plane localiser scan on the phantom.

> Proceed to plan the **3D GRE variable flip angle and dynamic** sequences according to figure 6 below.

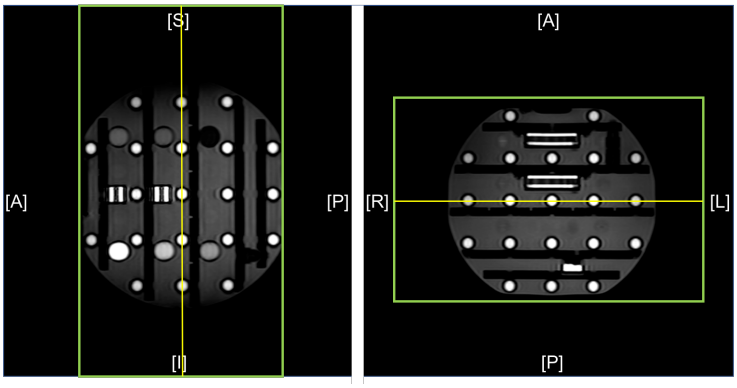

Figure 6: Alignment of the coronal images (right image) using the axial (left image) and sagittal (middle image) localisers.

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3.2.6 Scanning the qMRI phantom

> Proceed to run the DCE-MRI sequences in the plane defined in figure 6 and in the order illustrated in figure 3.

Key image acquisition parameters

	VFA T1 mapping acquisition			Dynamic acquisition
Parameter	**3D GRE FA1**	**3D GRE FA2**	**3D GRE FA3**	**FA3 dynamic series**
FOV (mm x mm)	365 x 450	365 x 450	365 x 450	365 x 450
Matrix size (X x Y x Z)	208 x 256 x 40	208 x 256 x 40	208 x 256 x 40	208 x 256 x 40
TR	minimum	As in 3D GRE FA1	As in 3D GRE FA1	As in 3D GRE FA1
TE	minimum	As in 3D GRE FA1	As in 3D GRE FA1	As in 3D GRE FA1
Repeats	3	3	3	3
Slice thickness (mm)	5	5	5	5

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3.2.7 Prescan settings

RF transmitter gains should be kept constant for the 3D GRE variable flip angle and dynamic series. If your scanner performs this automatically (***usually Siemens***), skip this section. If manual settings are required (***usually only for GE scanners and Philips***), please follow instructions below:

For Philips scanners:

- 3D GRE FA 1
  - In the workflow manager control panel, select the `Postprocessing` tab and set `Preparation Phases` to **`Full`**
  - Click `Accept`

- 3D GRE FA 2, FA 3 and FA 3 dynamic series
  - In the workflow manager control panel, select the `Postprocessing` tab and set `Preparation Phases` to **`Auto`**
  - Click `Accept`

For GE scanners:

- 3D GRE FA 1
  - In the workflow manager control panel, click the Scan arrow > **`Auto Prescan`**
  - Click Done

- 3D GRE FA 2, FA 3 and FA 3 dynamic series
  - In the workflow manager control panel, click the Scan arrow > **`Manual Prescan`**
  - Wait until a centre frequency peak is displayed
  - Click Done

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4 DATA SUBMISSION

4.1 DICOM Export

- Immediately after the end of a scan session, export the DICOM images according to your local procedures.

- Method of image transfer to Bioxydyn is not within the scope of this Imaging Manual

4.2 Image Transfer Schedule

Transfer all image sets **immediately** following the scans. This will allow us to provide image quality control feedback as soon as possible after the scan is acquired.

5 STUDY DOCUMENTATION

5.1 Image Acquisition Forms

In addition to this Imaging Manual, a 'Phantom Image Acquisition Form' will be supplied (see example in Appendix II).

The purpose of this acquisition form is to provide you with prompts during the MRI scan, particularly for positioning and relevant procedures.

6 CONTACT INFORMATION

6.1 Bioxydyn

A study-specific email address will be provided for phantom scanning issues.

7 REVISION HISTORY

Version	Date	Revision By	Changes from previous version
0.1	14th November 2017	Geoff Parker	Version created
0.2	24th November 2017	Geoff Parker, Sirisha Tadimalla, John Waterton	Updates after teleconference with Leeds
0.3	7th December 2017	Geoff Parker, Sirisha Tadimalla	Updates to text, figures, tables
0.4	8th December 2017	John Waterton	Updates to text
1.0	19th December 2017	Geoff Parker	Updates to text and diagrams. Version for TRISTAN WP2 use.

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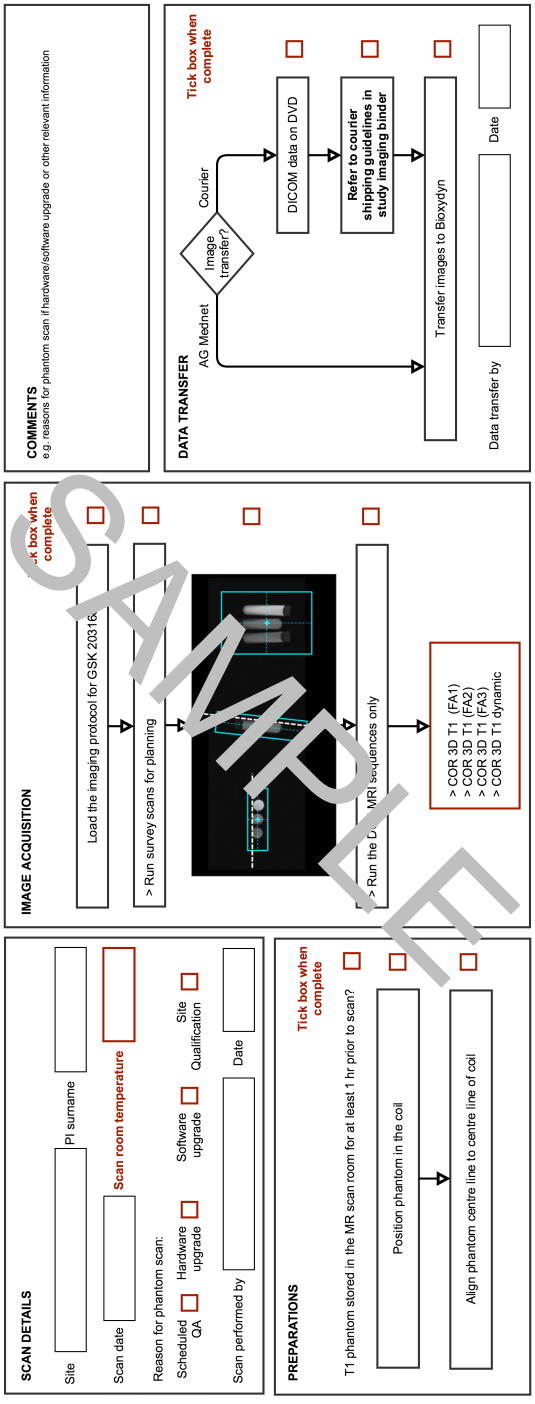
APPENDIX I: SCAN LIST FOR PHANTOMS

- Only the DCE-MRI scans need to be run (see below).
- **The same coil as is used for subject scans must be used for phantom scans** (e.g. knee coil, or hand/wrist coil).

Seq	Sequences	Approx scan time (min)
1	Localiser images	< 1:00
2	Coronal T1 GRE FA 1 (all phases/measurements)	1:00
3	Coronal T1 GRE FA 2 (all phases/measurements)	1:00
4	Coronal T1 GRE FA 3 (all phases/measurements)	1:00
5	Coronal T1 GRE FA 3 dynamic (*n* phases to cover scan duration)	10:00
	Total scan time	**~14:00**

APPENDIX: EXAMPLE PHANTOM IMAGE ACQUISITION FORM



NOTES

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APPROVAL*

Name	Title	Signature	Date
Heather Flynn	Head of Imaging Services, Bioxydyn		

* signed version kept with Bioxydyn