

Data Science Essentials: Resource Sheet

Unit	Resource Description	Link	
1.1	RWD and RWE definitions	https://www.newswise.com/articles/what-is-real-world-data-a-review-of-definitions http://www.abpi.org.uk/our-work/library/industry/documents/vision-for-real-world-data.pdf	Required
1.1	The ISPOR article on The Increasing Role of Real-World Evidence contains definitions and scope or RWE, as well as strengths and pitfalls (in tabular format).	https://www.ispor.org/research_pdfs/48/pdf/PHP280.pdf	Recommended
1.1	Blog -The Use of Real World Evidence in the European Context	http://blogs.lse.ac.uk/lseenterprise/files/2016/12/RWE_in_Europe_Paper1.pdf?utm_content=buffer82172&utm_medium=social&utm_source=linkedin.com&utm_campaign=buffer	Recommended
1.2	The ABPI Real Word Data Practical Guide provides further context for using real world data but also examples the advantages of RW data vs. RCT data, the possibilities in terms of RWE (e.g. Research vs. Audit vs. Service evaluation)	http://www.abpi.org.uk/our-work/library/guidelines/Documents/2011-06-13%20ABPI%20guidance%20-%20Demonstrating%20value%20with%20real%20world%20data.pdf	Required

1.2	Criteria for Distinguishing Effectiveness From Efficacy Trials in Systematic Reviews is a paper which highlights the difference between efficacy (ideal conditions in RCTs as required by regulators) and effectiveness (real world conditions as required by healthcare professionals).	https://www.ncbi.nlm.nih.gov/books/NBK44029/	Required
1.2	How we should look to evidence beyond RCTs	http://www.nejm.org/doi/full/10.1056/NEJMra1614394	Required
1.2	Paper in which researchers assess the evidence on the clinical effects of drug for hepatitis C (findings show that the RCTs have a high risk of bias which overestimate beneficial effects of DAAs and underestimate any potential harmful effects)	http://www.cochrane.org/CD012143/LIVER_direct-acting-antivirals-chronic-hepatitis-c	Required
1.2	GetReal project's RWE Navigator forumates how to use of RWE in effectiveness research, and provides recommendations to further advance evidence generation for innovative drugs.	https://rwe-navigator.eu/	Required
1.2	If you want to look at the evidence for clinical guidelines you may also want to look at GRADE	http://www.gradeworkinggroup.org/	Recommended
1.2	Link to papers using GRADE approach to evaluate the quality of observational (and RWE) evidence in research and the strength of recommendations.	http://annals.org/article.aspx?articleid=1310557 http://annals.org/aim/article/1657880/eradication-hepatitis-c-virus-infection-development-hepatocellular-carcinoma-meta-analysis http://www.ncbi.nlm.nih.gov/pubmed/26827182	Recommended
1.2	The ISPOR Real World Data Task Force Report describes the development of a framework using real	https://www.ispor.org/workpaper/RWD_TF/RWTFManuscript.pdf	Recommended

	world data to support healthcare coverage and payment decisions in the US -and is therefore an example of the potential of RWE to improve healthcare.		
1.2	The Academy of Medical Sciences also provides details of policy projects which have been carried out using real world data	https://acmedsci.ac.uk/policy/policy-projects/real-world-data	Recommended
1.3	Deloitte's Real-World Evidence Benchmark Survey 2017	https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-2017-real-world-evidence-survey.pdf	Required
1.3	BMJ Rapid Response for definition of comparative effectiveness research	http://www.bmj.com/rapid-response/2011/11/03/definition-comparative-effectiveness-research	Required
1.5	Market Access Articles published by the Pharmaceutical Marketing Society: Industry and the NHS - can promotion and partnership co-exists?	1. http://pmsociety.org.uk/article/industry-and-the-nhs-promotion-and-partnership	Required
1.5	Market Access Articles published by the Pharmaceutical Marketing Society: The Future of Market Access – Payers, Patients, Pharmas	http://pmsociety.org.uk/article/the-future-of-market-access-payers-patients-pharma-report	Required
1.5	Market Access Articles published by the Pharmaceutical Marketing Society: Market access: please no more talk of 'hurdles' and 'obstacles'	http://pmsociety.org.uk/article/market-access-please-no-more-talk-of-hurdles-and-obstacles	Required
1.5	This article covers key points around Market Access' need for RWE and public trust.	https://invivo.pharmamedtechbi.com/IV004954/RealWorldEvidence-And-The-Quest-For-European-Market-Access	Required
1.5	The Pharmaceutical Marketing Society website provides further information on Market Access	https://pmsociety.org.uk/market-access	Recommended

	including current working definitions		
1.5	This article covers; how industry can optimise market access by analysing real world trends in different treatment spaces; industry factors encouraging R&D; issues facing industry	http://www.outsourcing-pharma.com/Commercial-Services/Real-world-data-studies-could-revitalize-productivity	Recommended
1.6	We recommend watching both Youtube videos posted by the IBD Registry Board in their entirety. They look at 1. Driving Excellence with the IBD Registry (e.g. producing clinical summaries useful to both patients and clinicians, providing better monitoring and outcomes data etc) 2. Audit & Registry – Where next? (e.g. what can be done in research/for patients by unified concerted efforts)	https://youtu.be/83wUieuol8g https://youtu.be/chA0_LVclAw	Required
1.7	Pharmaceutical Marketing Society's Market Access definitions survey (2017)	https://pmsociety.org.uk/article/the-pm-society-market-access-survey-2017-results	Required
1.8	This Deloitte's article may be helpful to discussion as it look at how RWE can enable the life sciences / industry to transform patient care.	https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/real-world-evidence.html	Required
1.8	Imperial College Health Partners' initiative to improve the current rehabilitation care pathway for acquired brain injury (ABI)	http://atlas.ahsnnetwork.com/neurorehabilitation/	Recommended
1.8	Adaptive Licensing Definition	http://www.abpi.org.uk/our-work/library/industry/Documents/onestopshop_adaptive_licensing.pdf	Recommended
1.8	Early Access to Medicines Scheme Principles	https://www.gov.uk/government/publications/early-access-to-medicines-scheme-eams-how-the-scheme-works/early-access-to-medicines-scheme-eams-task-group-and-principle	

2.1	<p>This link includes essential reading regarding data security awareness and covers:</p> <ol style="list-style-type: none"> 1 The principles and terminology of information governance (IG). 2 Basic data security / cyber security terminology. 3 The importance of data security to patient/service user care. 4 That law and national guidance requires personal information to be protected 	https://www.igt.hscic.gov.uk/ (powerpoint)	Required
2.1	This report specifically looks at data governance arrangements in relation to RWE and looks at policy/law globally/EU and country level.	https://www.ohe.org/publications/data-governance-arrangements-real-world-evidence	Recommended
2.2	These links include essential reading regarding data protection and data security awareness, GDPR and Caldicott which should be read in their entirety	https://ico.org.uk/for-organisations/guide-to-data-protection/ https://ico.org.uk/for-organisations/guide-to-data-protection/conditions-for-processing/ https://ico.org.uk/for-organisations/guide-to-data-protection/principle-6-rights/subject-access-request/ https://ico.org.uk/for-organisations/guide-to-data-protection/principle-6-rights/damage-or-distress/ https://ico.org.uk/for-organisations/guide-to-data-protection/principle-6-rights/preventing-direct-marketing/ https://ico.org.uk/for-organisations/guide-to-data-protection/principle-6-rights/automated-decision-taking/ https://ico.org.uk/for-organisations/guide-to-data-protection/principle-6-rights/correcting-inaccurate-personal-data	Required

		https://ico.org.uk/for-organisations/guide-to-data-protection/principle-6-rights/compensation https://ico.org.uk/media/for-organisations/documents/1546/data-controllers-and-data-processors-dp-guidance.pdf	
2.2	These links include essential reading regarding GDPR	https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/ https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/the-right-to-be-informed https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/the-right-to-rectification https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/the-right-to-erasure https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/the-right-to-restrict-processing/ https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/the-right-to-data-portability/ https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/the-right-to-	Recommended

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2.2	These links include essential reading regarding Caldicott	https://www.igt.hscic.gov.uk/Caldicott2Principles.aspx?tk=429286257340365&Inv=18&cb=1540aa1f-3697-4f9d-9865-c9304b732cc1 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/535024/data-security-review_PD https://www.igt.hscic.gov.uk/ (powerpoint) https://pharmaphorum.com/views-and-analysis/health-care-innovation-needs-block-chain/#	Required
2.2	Article on Brexit: Data protection and cyber security law implications	https://www.twobirds.com/en/news/articles/2016/uk/brexit-data-protection-and-cyber-security-law-implications	Recommended
2.2	Allen & Overy's General Data Protection Regulation	http://www.allenoverly.com/SiteCollectionDocuments/	Recommended

	Guide	Radical%20changes%20to%20European%20data%20protection%20legislation.pdf	
2.2	Article on the Queen's Speech and the promised "Data Protection (Exemptions from GDPR) Bill	http://amberhawk.typepad.com/amberhawk/2017/06/queens-speech-and-the-promised-data-protection-exemptions-from-gdpr-bill.html	Recommended
2.2	NHS Digital's Disclosure Control Procedure of personal data	http://content.digital.nhs.uk/media/23395/Disclosure-Control-Procedure/pdf/Disclosure_Control_Procedure.pdf	Recommended
2.2	Article on Drawing the Line between Identifying and Non-identifying Data	http://webarchive.nationalarchives.gov.uk/+http://www.isb.nhs.uk/documents/isb-1523/amd-20-2010/1523202010guid.pdf	Recommended
2.3	Article on Google DeepMind and the Royal Free: A Cautionary Tale	https://phys.org/news/2017-03-deepmind-royal-free-cautionary-tale-health.html	Required
2.3	This is an article focused on RWE and the (patient) privacy predicament	http://www.ey.com/Publication/vwLUAssets/ey-real-world-evidence-the-privacy-predicament/\$FILE/ey-real-world-evidence-the-privacy-predicament.pdf	Recommended
2.3	Patient and patient involvement in research using secondary-use data	https://simondenegri.com/2017/08/03/getting-a-gripp2-on-public-involvement-reporting-in-research-papers/amp/ https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-017-0062-2	Recommended
2.4	Article on "Inexcusable" mistakes made in Google DeepMind and Royal Free NHS data deal – Study	https://www.digitalhealth.net/2017/03/deepmind-health-royal-frees-criticised-lack-patient-involvement/	Required

2.4	Real-world evidence: the privacy predicament. Implications of data privacy regulations and the management of associated risks	http://www.ey.com/Publication/vwLUAssets/ey-real-world-evidence-the-privacy-predicament/\$FILE/ey-real-world-evidence-the-privacy-predicament.pdf	Required
2.4	Article describing how Google DeepMind's first deal with the NHS has been torn apart in a new academic study	http://uk.businessinsider.com/deepmind-royal-free-london-nhs-deal-inexcusable-mistakes-2017-3	Recommended
3.1	The Health Data Finder provides summary information about key NHS datasets such as context of data collected, extraction frequency, type of data, coverage, geography, volume, granularity, access, consent etc.	http://www.hdf.nihr.ac.uk/datasets	Required
3.1	An index of where to find publicly available health and care data (links provided) and which organisations are responsible for the data.	https://digital.nhs.uk/media/31778/NHS-Digital-Guide-For-Journalists-2017/pdf/80477_NHSDigital_Guide_for_journos-2017_electronic_FINAL	Required
3.1	Link to Understanding Patient Data website which provides information about the uses of health information and how and why data can be used for care and research whilst protecting privacy	https://understandingpatientdata.org.uk/about-us	Required
3.1	NHS Digital's introduction to HES	http://content.digital.nhs.uk/hes	Recommended
3.1	NHS Digital's introduction to GP QoF data	http://qof.digital.nhs.uk/	Recommended
3.1	NHS Digital's introduction to Prescribing data	http://content.digital.nhs.uk/prescribing	Recommended
3.1	Article profiling CPRD	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4521131/	Recommended

3.3	NHS Digital's HES Analysis Guide (all 22 pages are relevant). The guide: 1 Presents an overview of the data available in HES 2 Describes the sensitivities of some of this data 3 Defines the limits up to which data can be released without risk of encountering problems with those sensitivities 4 Gives rules for releasing HES data 5 Outlines some of the data quality and integrity issues.	http://content.digital.nhs.uk/media/1592/HES-analysis-guide/pdf/HES_Analysis_Guide_Jan_2014.pdf	Required
3.4	This is a consultation document which contains information regarding: 1 Current Hospital Datasets 2 Future Hospital Extracts 3 International Context 4 HES processing and outputs 5 Example Data Set 6 Uses of HES Data 7 HES data quality 8 International Case Studies 9 Glossary of Terms	http://content.digital.nhs.uk/media/1592/HES-analysis-guide/pdf/HES_Analysis_Guide_Jan_2014.pdf	Recommended
3.5	Link to .Quality Outcomes Framework in the GP data hub	https://digital.nhs.uk/GP-data-hub/quality-outcomes-fr amework-in-GP-data-hub	Required
3.5	Link to Dementia 65+ Estimated Diagnosis Rate Indicator in the GP data hub	https://digital.nhs.uk/GP-data-hub/Dementia-65-Estim ated-Diagnosis-Rate-Indicator	Required
3.5	Hospital Estates and Facilities Statistics	http://hefs.hscic.gov.uk/ERIC.asp/ http://hefs.hscic.gov.uk/PLACE.asp	Required
3.5	Open Prescribing(BI Tool)	https://openprescribing.net	Required

3.5	Link to NHS Digital's data and information strategy which aims for better data, better access. Key areas in report include: 1 Data content 2 Data access 3 Analysis 4 Data science	https://digital.nhs.uk/data-and-information/strategy	Recommended
3.6	The whole article is relevant to the discussion point: Are Real-World Data and Evidence Good Enough to Inform Health Care and Health Policy Decision-Making?	https://link.springer.com/chapter/10.1007/978-981-10-3262-2_8	Recommended
3.7	Open Data Institute's definition of open data	http://theodi.org/what-is-open-data	Required
3.7	Open Data Institute's definition of open data (in depth)	http://opendefinition.org/	Recommended
3.8	Open Data in the Health Sector Report (2017) to include open data recommendations to data publishers	http://openhealthcare.org.uk/open-data-in-the-health-sector/	Required
3.8	UK Government's Open Standards Principles: a What open standards help to deliver b Open Standards Principles	https://www.gov.uk/government/publications/open-standards-principles/open-standards-principles	Recommended
3.8	European Interoperability Framework (EU Commission)	https://ec.europa.eu/isa2/eif_en	Recommended
3.8	Interoperability Toolkit (UK NHS)	https://digital.nhs.uk/interoperability-toolkit	Recommended
3.8	ONC Standards and Interoperability Framework (US Government)	https://www.healthit.gov/sites/default/files/pdf/fact-sheets/standards-and-interoperability-framework.pdf	Recommended

3.8	SNOMED CT (Clinical Coding)	http://www.snomed.org/snomed-ct/what-is-snomed-c	Recommended
3.8	ICD (International Statistical Classification of Diseases and Related Health Problems)	http://www.who.int/classifications/icd/en/	Recommended
3.8	UK READ Codes (GP clinical coding)	https://digital.nhs.uk/article/1104/Read-Codes	Recommended
3.8	HL7 Messaging (Healthcare Interoperability)	http://www.hl7.org/documentcenter/public_temp_F492D7D6-1C23-BA17-0C3158565321647B/calendarofevents/himss/2012/SNOMED%20CT%20and%20HL7%20--%20Bringing%20Standards%20Together.pdf	Recommended
3.8	Open Data Handbook	http://opendatahandbook.org/guide/en/what-is-open-data/	Recommended
3.8	Supporting open data and transparency (NHS)	http://content.digital.nhs.uk/transparency	Recommended
3.8	UK National Statistician's Guidance (Open Data)	https://www.statisticsauthority.gov.uk/national-statistician/ns-reports-reviews-guidance-and-advisory-committees/national-statisticians-guidance/	Recommended
3.9	European Medicines Agency: Information Management Strategy	http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_001702.jsp&mid=WC0b01ac0580ae7752	Recommended
3.9	A-Z of NHS Digital Official and National Statistics Publications (multiple sources of open data)	http://content.digital.nhs.uk/statisticsa-z	Recommended
4.0	GetReal project's newly released policy recommendations relating to real-world evidence.	www.imi-getreal.eu http://www.imi-getreal.eu/Portals/1/Documents/01%20deliverables/2017-03-29%20-%20WP1%20-%20Adva	Recommended

		ncing%20Evidence%20Generation%20for%20New%20Drugs.pdf http://www.imi-getreal.eu/News/ID/80/Policy-recommendations-from-WP1-Policy-Expert-Group-online	
4.0	GetReal project's Directory or Resources	https://rwe-navigator.eu/directoryofresources/	Recommended