Research project and proposal writing workshop

Andy Gray
Division of Pharmacology
Discipline of Pharmaceutical Sciences

MURIA is a multidisciplinary network of people striving to promote sustainable, rational medicine use in Africa through collaborative research and capacity building in order to improve the quality of life of patients, as well as the quality of medicine utilisation in Africa.

Timing

- **Monday 26 June 2017 – Track 2B**
- 13h15 – 13h30 - Introductions
- 13h30 – 13h45 - Why do we need a research proposal at all?
- 13h45 – 14h15 – Elements of a successful (and useful) research proposal
- 14h15 – 15h15 - Working through the elements, one-by-one and reflecting on two completed projects

Reflecting on two recent papers

Int J Clin Pharm (2016) 38:880–887
DOI 10.1007/s11096-016-0304-7

RESEARCH ARTICLE

Resource use and cost of care with biologicals in Crohn's disease in South Africa: a retrospective analysis from a payer perspective

Jacqui Miot[1,2] · Susan Smith[2] · Niri Rhimsan[2]

Received: 20 November 2015 / Accepted: 13 April 2016 / Published online: 27 April 2016

Abstract *Background* Crohn's disease is a relapsing remitting inflammatory disease of the gastrointestinal tract. Treatment may require expensive biological therapy in severe patients. Affordability of the high cost anti-TNF-α agents has raised concerns although evidence suggests cost-offsets can be achieved. There is little information on the resource utilisation of Crohn's patients in low and middle income countries. *Objective* The objective of this study is to investigate the resource utilisation and costs associated with biologicals treatment of Crohn's disease. *Setting* The setting for this study is in private healthcare in South Africa from a payer perspective. *Method* A retrospective longitudinal analysis of an administrative claims database from a large private healthcare insurer of patients who had at least 1 year claims exposure prior to starting biologicals and 2 years follow-up thereafter. Resource utilisation and costs including total Crohn's costs, hospital admissions and surgery, out of hospital costs, biologicals and chronic medicines were analysed. *Main outcome measure* The primary objective was to compare the change in resource utilisation and costs for Crohn's related conditions before and after starting biological treatment. *Results* A cohort of 72 patients was identified with a 35% ($p = 0.005$) reduction in Crohn's related costs (excluding the cost of biologicals) from ZAR 55,925 (US$3690) 1 year before compared to ZAR 36,293 (US$4684) 2 years after starting biological medicines. However, inclusion of the cost of biologicals more than doubled the total costs to ZAR 150,915 (± 91,642) US$14,488 (± 8798) in Year 2. Significant reductions in out-of hospital Crohn's related spend was also observed. *Conclusions* A reduction in healthcare costs is seen following starting biologicals in patients with moderate to severe Crohn's disease. However, the high cost of biological therapy outweighs any possible savings achieved in other areas of healthcare utilisation.

Keywords Biologicals · Clinical pharmacology · Cost · Crohn's disease · Pharmacoeconomics · South Africa

Impacts on practice

- Increased awareness of the incremental costs of treating patients with biologicals could lead to more engagement around targeted use by healthcare professionals.
- Particularly in low-middle income countries where affordability is a major concern, strategies may need to be adapted to look at outcomes based models based on the finding that the cost outweighs the savings by a considerable amount.
- Alternative funding structures (e.g. including patient co-payments) may need to be developed or implemented to provide increased access to the biologicals in Crohn's disease in South Africa.

Introduction

Crohn's disease is a relapsing remitting chronic inflammatory disease of the gastrointestinal tract. Symptoms include abdominal pain, fever, diarrhoea and cramps which

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Int J Clin Pharm (2016) 38:865–869
DOI 10.1007/s11096-016-0298-1

RESEARCH ARTICLE

Prescribing patterns of non-steroidal anti-inflammatory drugs in chronic kidney disease patients in the South African private sector

Willem P. Meuwesen[1] · Jessica M. du Plessis[1] · Johanita R. Burger[1] · Martie S. Labbe[1] · Marike Cockeran[1]

Received: 29 September 2015 / Accepted: 29 March 2016 / Published online: 18 April 2016

Abstract *Background* Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most commonly used pharmaceutical agents worldwide. NSAIDs are considered nephrotoxic and should therefore be used with caution or be avoided completely in high risk patients, such as chronic kidney disease (CKD) patients. *Objective* This study aimed to investigate the prescribing of NSAIDs in CKD patients in order to generate awareness and improve the outcome of these patients. *Setting* The study was conducted using medicine claims data in the private health sector of South Africa. *Method* A descriptive, quantitative study was performed, using retrospective data obtained from a Pharmaceutical Benefit Management company. Data from 1 January 2009 to 31 December 2013 were analysed. The study population consisted of all patients with an ICD-10 code for a CKD (N18), in association with a paid claim for an NSAID. *Main outcome measure* The stratification of NSAID prescribing volume among the CKD population in terms of gender, age, NSAID type, dosage and prescriber type. *Results* The prescribing of NSAIDs in CKD patients varied between 26 and 40 % over the 5 year study period. No association between gender and CKD patients who received NSAIDs versus those who did not was found, with $p > 0.05$ and Cramer's $V < 0.1$ for each year of the study. The association between age groups and CKD patients who received NSAIDs versus those who did not was statistically significant, but practically weak ($p < 0.05$; Cramer's $V \geq 0.1$). Most NSAID prescriptions (52–63 %) were for patients aged 35–64 years. Diclofenac (34.25 %) was the single most frequently prescribed NSAID, but the COX-2-inhibitors (celecoxib, meloxicam and etoricoxib) were the preferred NSAID class to be prescribed. The majority (61.6 %) of the NSAIDs were prescribed by general medical practitioners in dosages meeting and even exceeding the recommended daily dosage of patients with normal kidney function. *Conclusions* Even though NSAIDs are regarded as nephrotoxic drugs, they are still being prescribed to at-risk CKD patients, in particular, the elderly.

Keywords Chronic kidney disease · Non-steroidal anti-inflammatory drugs · NSAIDs · Private health sector · South Africa

Impact of findings on practice

- Every three to four patients with chronic kidney disease in South Africa are being prescribed NSAIDs in dosages similar to, and exceeding, the recommended daily dosages for patients with a normal kidney function.
- Greater caution should be practised by general medical practitioners and dispensing pharmacists in South Africa when treating pain in patients with chronic kidney disease, with regard to the type and dosage of drug prescribed.

Introduction

Non-steroidal anti-inflammatory drugs (NSAIDs) are regarded as the most commonly used pharmaceutical agents for the treatment of pain and inflammation worldwide [1, 2]. NSAIDs which include, *inter alia*, ibuprofen,

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Introductions

- Short description of
  - who you are
  - where you work
  - what your professional background is
  - what **medicines utilisation research** activities you are currently engaged in (or plan to be engaged in)

Why do we need a research proposal (protocol) at all?

ON THE ART OF WRITING PROPOSALS

https://s3.amazonaws.com/ssrc-cdn1/crmuploads/new_publication_3/%7B7A9CB4F4-815F-DE11-BD80-001CC477EC70%7D.pdf

- “A proposal's overt function is to persuade a committee of scholars that the project shines with the three kinds of merit all disciplines value, namely, conceptual innovation, methodological rigor, and rich, substantive content. But to make these points stick, a proposal writer needs a feel for the unspoken customs, norms, and needs that govern the selection process itself.”

Elements of a successful (and useful) research proposal

- Title Page
- Introduction, Context, and Problem
- Research Question or Hypotheses
- Aim & Objectives
- Literature Review
- Theoretical/Conceptual Framework
- Study Design
- Limitations
- Significance and Novelty of the Work
- Ethical Considerations
- Dissemination
- References
- Appendices

NOTE:

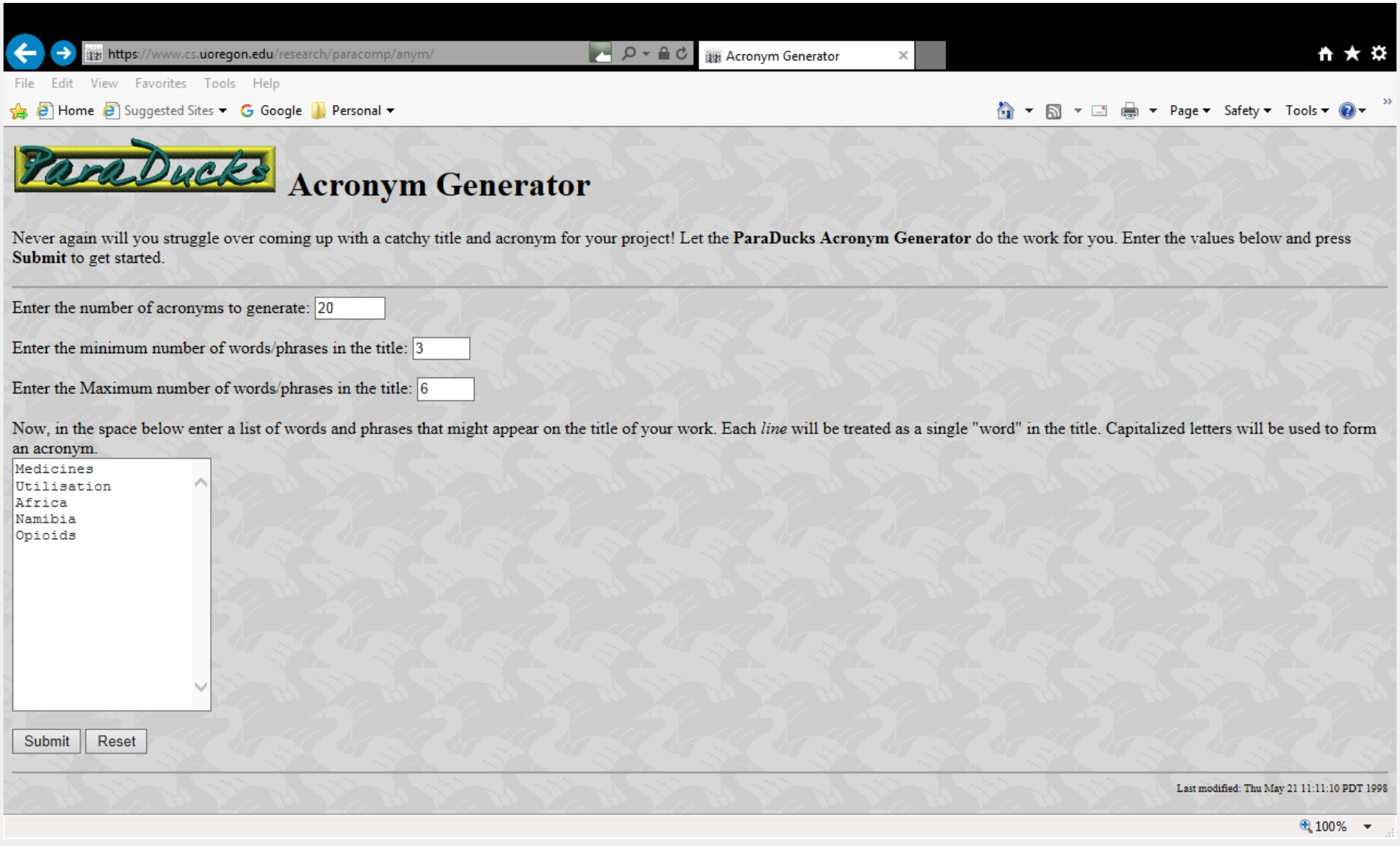
- This is but one of many formats (the one currently used in the UKZN online Masters programme in the School of Health Sciences).
- There are many others, and each has its strengths and weaknesses.
- Understand the needs of your institution or the proposed funder of your research.

Title page

- project title

Note: To decide on a title, consider focusing on one of five ways to derive a name: by emphasising

1) the problem
2) the method
3) the aim
4) the result (works better when you are writing up afterwards)
5) a combination of aim and method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Acronym Generator
Never again will you struggle over coming up with a catchy title and acronym for your project! Let the ParaDucks Acronym Generator do the work for you. Enter the values below and press Submit to get started.
Enter the number of acronyms to generate: 20
Enter the minimum number of words/phrases in the title: 3
Enter the Maximum number of words/phrases in the title: 6
Now, in the space below enter a list of words and phrases that might appear on the title of your work. Each line will be treated as a single "word" in the title. Capitalized letters will be used to form an acronym.
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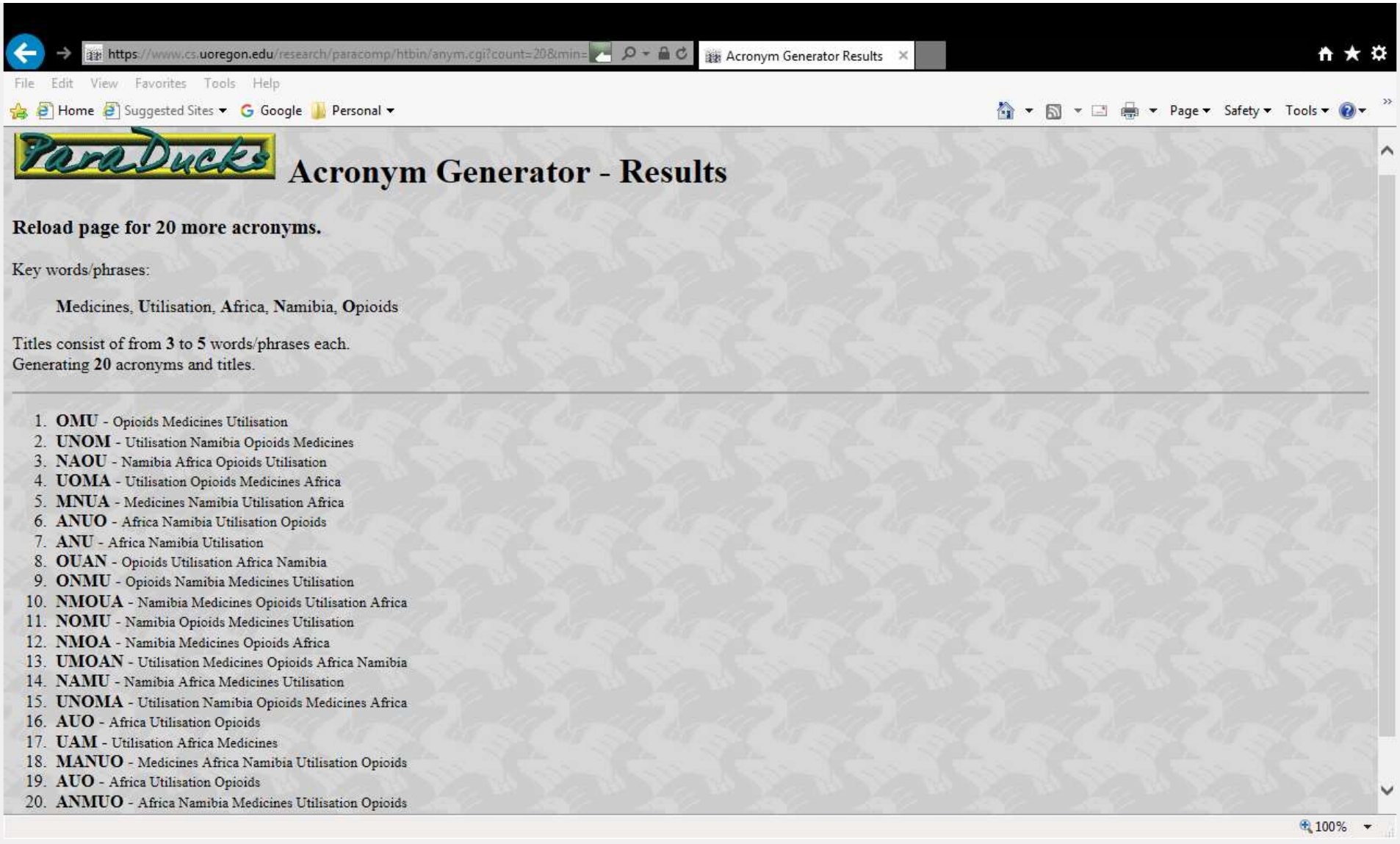
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Acronym Generator Results
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Page Safety Tools
ParaDucks
Acronym Generator - Results
Reload page for 20 more acronyms.
Key words/phrases:
Medicines, Utilisation, Africa, Namibia, Opioids
Titles consist of from 3 to 5 words/phrases each.
Generating 20 acronyms and titles.
1. OMU - Opioids Medicines Utilisation
2. UNOM - Utilisation Namibia Opioids Medicines
3. NAOU - Namibia Africa Opioids Utilisation
4. UOMA - Utilisation Opioids Medicines Africa
5. MNUA - Medicines Namibia Utilisation Africa
6. ANUO - Africa Namibia Utilisation Opioids
7. ANU - Africa Namibia Utilisation
8. OUAN - Opioids Utilisation Africa Namibia
9. ONMU - Opioids Namibia Medicines Utilisation
10. NMOUA - Namibia Medicines Opioids Utilisation Africa
11. NOMU - Namibia Opioids Medicines Utilisation
12. NMOA - Namibia Medicines Opioids Africa
13. UMOAN - Utilisation Medicines Opioids Africa Namibia
14. NAMU - Namibia Africa Medicines Utilisation
15. UNOMA - Utilisation Namibia Opioids Medicines Africa
16. AUO - Africa Utilisation Opioids
17. UAM - Utilisation Africa Medicines
18. MANUO - Medicines Africa Namibia Utilisation Opioids
19. AUO - Africa Utilisation Opioids
20. ANMUO - Africa Namibia Medicines Utilisation Opioids
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Introduction, Context, and Problem

- Give a brief overview/summary of the larger question/problem/enquiry in the field and how your study fits into this arena. It should provide sufficient information to set the scene for your aims, objectives and hypotheses
  - What is the bigger issue or problem that the project addresses?
  - Why is this an important or beneficial study in the context of the bigger issue?
  - Define or describe the main terms or concepts addressed in the body of the proposal
- *Include information the reader needs to know in order to form a mental picture of the context of your research.*

Introduction, Context, and Problem (2)

- Can contain descriptive background information relevant to the topic that does not necessarily fit into the literature review.
  - for example, you can provide information on incidence and prevalence of relevant diseases or conditions, medicines usage/adherence information, geographic or demographic information that helps the reader understand the context of your research.

Introduction, Context, and Problem (3)

- This section should end with a clear problem statement, that contextualizes the problem in your study area and clearly indicates the gaps that you are intending to address
  - make sure the information in the problem statement is conceptually similar to the research questions/hypothesis

Research Question or Hypotheses

- Research Questions (preferably 1, and maximum 3)
  - generally associated with qualitative or mixed methods research, where the results could be any number of options.
  - research questions need to be aligned with the problem and the Aim, so that the answer to the question addresses the problem.

Research Question or Hypotheses (2)

- Hypotheses
  - are generally associated with quantitative analysis only
  - usually written in the form of a null hypothesis (that the opposite of the hypothesis is true).
  - where applicable, state the relationship that you expect to exist between the dependent and the independent variables as clearly as possible.

Note: The research questions or hypotheses should be conceptually similar to the project aim.

Aim & Objectives

- Aim
  - is the broad vision or goal to which the project will contribute, and is a clear and concise statement about the broader purpose of your study
  - a project usually has 1 overarching aim

Aim & Objectives (2)

- Objectives
  - are well-defined statements of intended measurable change/information accumulation to be accomplished under the scope of the current project
  - are measureable steps toward achieving the project aim
  - should be very specific and achievable within the study period
  - worded in such a way that you indicate what you are measuring, how you will measure it, and when it will be achieved (i.e. by the end of the study period)

Literature Review

- The literature review of a research proposal has two main purposes:
  - inform the way you do your study
  - provide studies against which you can compare your findings

Literature Review (2)

- Identify research studies that address key elements of your proposed research.
  - What is known about your topic?

Literature Review (3)

- Spell out previous studies'/authors' arguments and methods:
  - Describe key points relevant studies make and how they have come to their conclusions
  - Compare what different research studies conclude about the issue
  - Describe patterns and strengths in previous research findings
  - Describe gaps and weaknesses in previous research findings
  - Indicate the methodologies used in other studies

Literature Review (4)

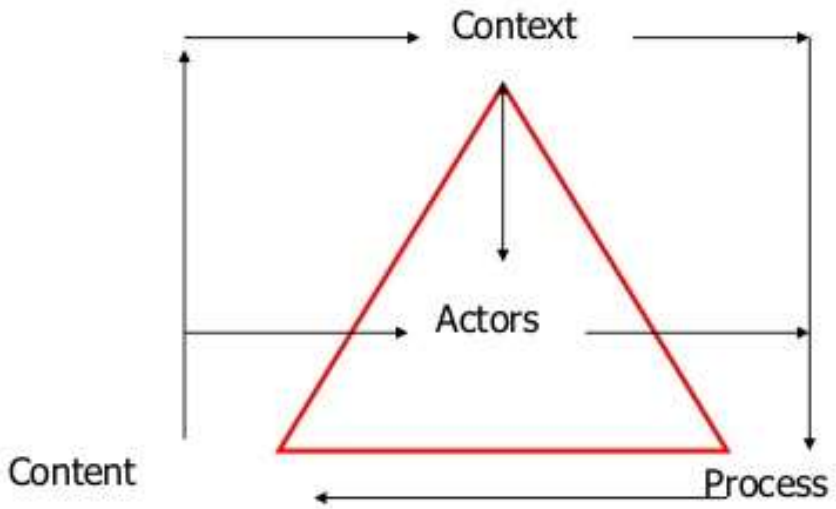
- Options for organising the literature review
  - ***geographic***: begin your review in a global geographic context, then narrow to developed countries, developing countries, regional, national, and local studies.
  - ***historical or chronological***: trace the history of developments around your research topic and include cutting edge/recent developments
  - ***thematic:*** describe relevant or common themes/findings/patterns in the literature. The themes you describe must be directly related to your aims and objectives.
  - ***method, approach or model:*** are there particular methods, models or approaches relevant to your study? Are you testing a model or method that will feature prominently in your study approach?

Theoretical/Conceptual Framework

- Theory provides an explanatory framework that will help guide you in structuring your work so that you can describe what you observe in the data and identify any associations between variables (though not necessarily causality).
  - Choose one theory or conceptual framework
  - Describe the key points of the theory succinctly
  - Cite key literature as background to the description of the theory
  - Clearly indicate how the theory/framework informs your study design, analysis and conclusions

Socio-Ecological Model

The Policy Triangle



Walt G and Gilson L, Reforming the health sector in developing countries: the central role of policy analysis, Health Policy and Planning 1994; 9: 353-70

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Study Design

- Every sub-heading may not apply to every proposal – but asking about each helps!
- ***Setting***
  - Where will your study take place?
- ***Subjects/Participants***
  - What/who is your population?
  - What/who is your sample?
  - Why these participants?
  - What process will you use to recruit study participants?

Study Design (2)

- ***Sampling***
  - How will you draw/select your sample? What sampling methods will you use?
  - Justify the use of the chosen sampling method
  - Specify **inclusion** and **exclusion** criteria.
  - How big will your sample size be and why this size?

This is where help from a statistician is INVALUABLE!

Study Design (3)

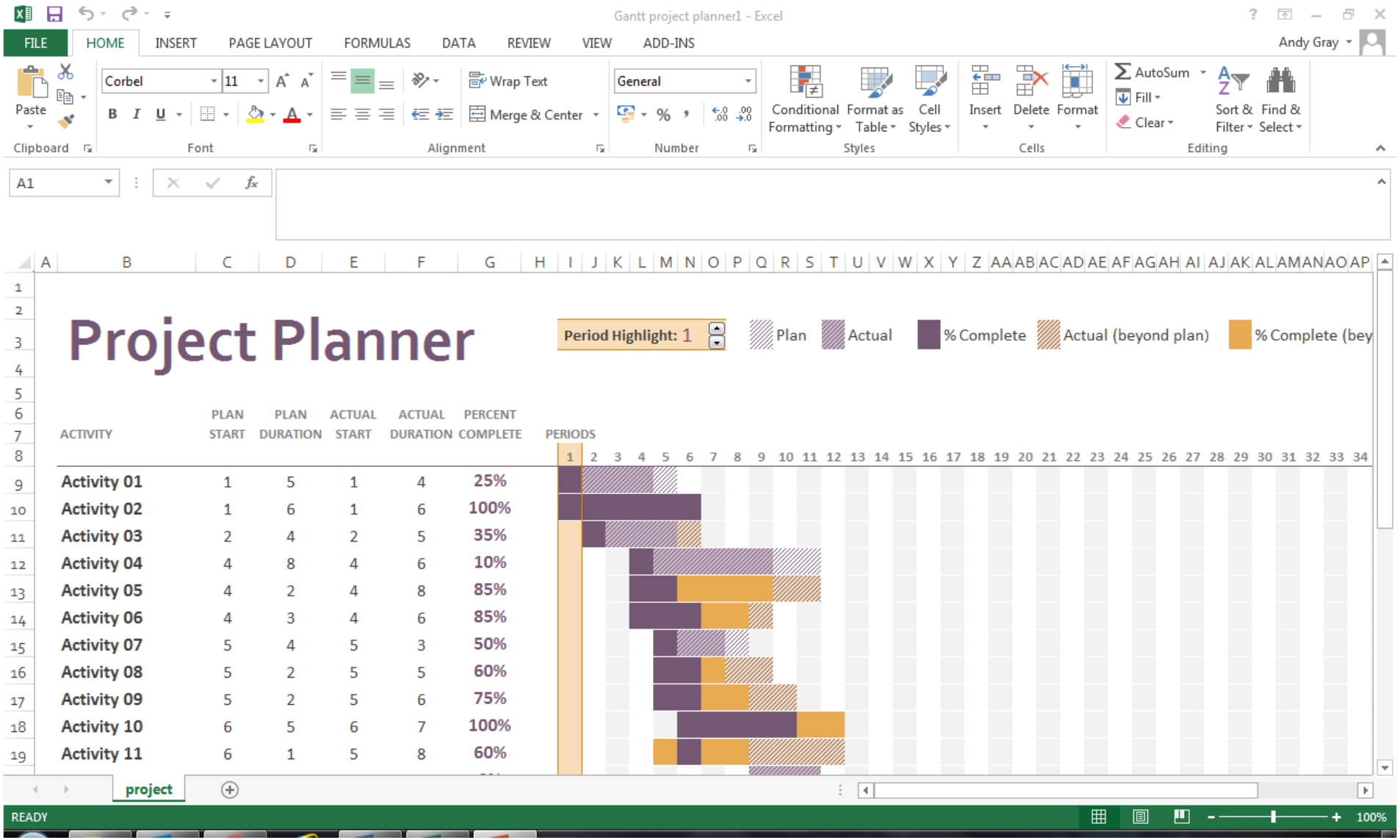
- ***Data Collection Tool/Methods***
  - indicate **all** the collection tools (such as questionnaires) and the type of data that they will collect (demographic, clinical, etc.) - include as appendices
  - for questionnaires, indicate the themes that you are going to use to collect the data so that there is a clear link between the content this data collection tool and relevant literature or theory
  - if you are collecting both qualitative and quantitative data, be sure to describe the relationship between the two; that is, how collecting one type of data will inform or relate to the other type

Study Design (4)

- ***Data Collection Tool/Methods (contd)***
  - discuss the reliability and validity of instruments and procedures, and of entire method. State whether the tools have been validated. Will the results be generalizable and replicable? Include any tool development steps.
  - if you are developing an intervention, describe how you will develop it, what baseline data will be collected, what variables you will be measuring, the control/comparisons.

Study Design (5)

- ***Pilot Study***
  - On what sample profile and size will you test your data collection tools?
- ***Timeline***
  - Over what period will you collect different types of data? Consider proving a **Gantt chart** to graphically illustrate your timeline.


Gantt project planner1 - Excel
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Andy Gray
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Activity 10 6 5 6 7 100%
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project
READY
100%

Study Design (6)

- Describe the process you will follow to collect the data on the tools identified above. This can be described in a number of ways:
  - phases or steps: What will data will be collected first and how? What data will be collected second and how? What data will be collected third…
  - by objective
  - if you are conducting an intervention, clearly describe how it will be administered, how long the intervention will last, (and any standard of care practices that apply), and what safeguards will be in place for those who participate.

Study Design (7)

- **Data Analysis**
  - What analytical techniques will you use for the qualitative and quantitative data and why?
  - What statistical techniques will be used, why and what computer packages?
  - How you will evaluate the intervention for impact?
  - What is the planned presentation of the results?

Study Design (8)

- **Data Management**
  - How will the raw data be treated/managed (data entry, cleaning, etc)?
  - How and where will the data be stored, in what form, who will have access, how long the data will be held and how it will be disposed of?

Limitations

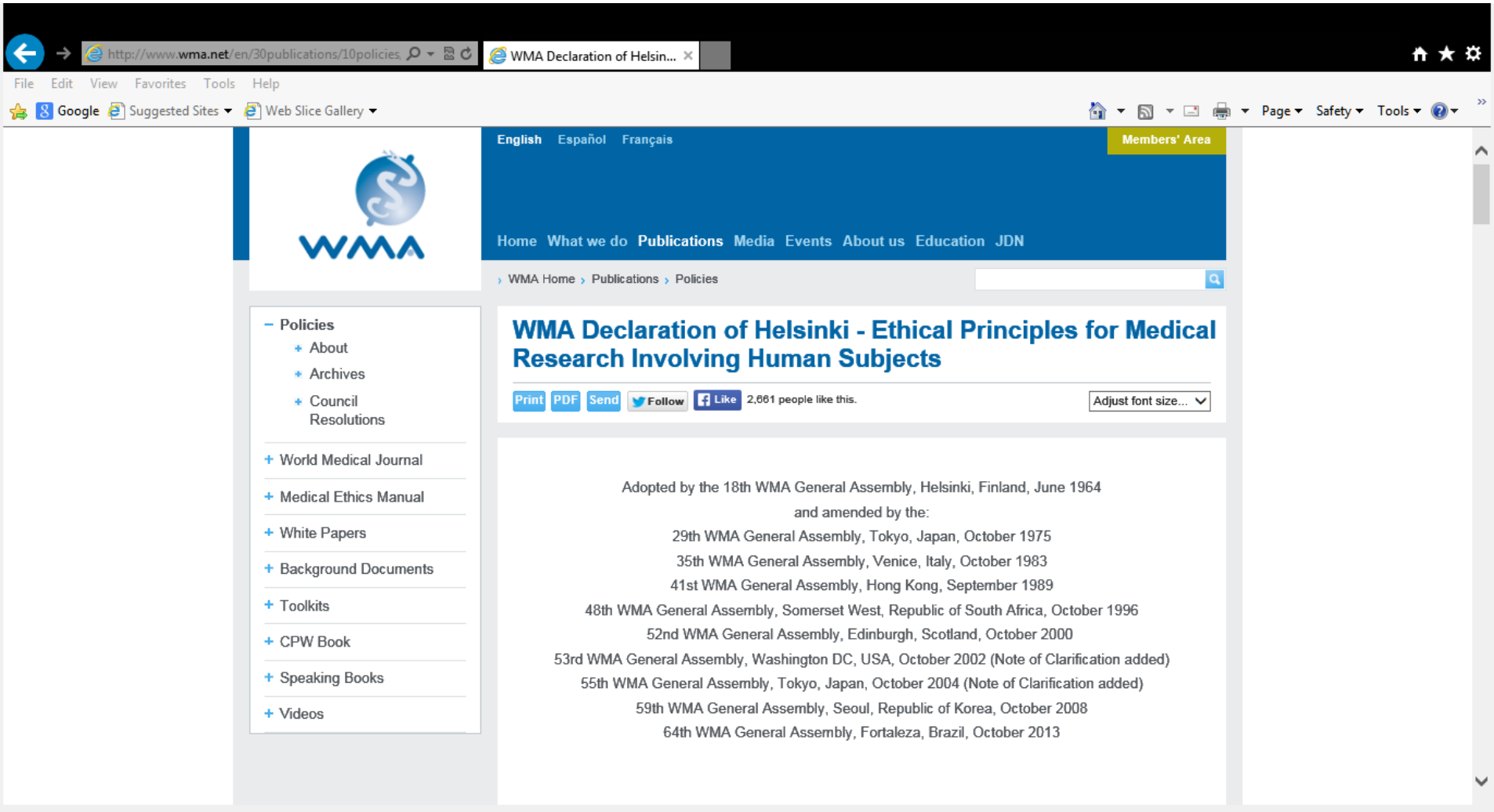
- What factors may impact on your study and how (sample size, funding, time constraints, lost data, inadequate samples)?

Significance and Novelty of the Work

- Describe how your work will contribute to the existing knowledge or literature on the topic
- Address how your work will fill the gaps in existing knowledge and advance knowledge specifically in your discipline
- Make references to some of the studies that you have mentioned in your literature review and note how your work will complement or contrast with existing findings

Ethical Considerations

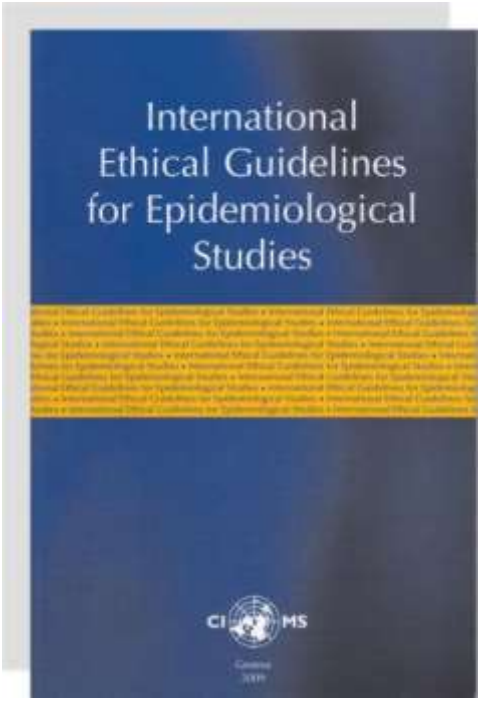
- What ethical considerations are relevant in your study?
- How will participant confidentiality and privacy be assured?
- What informed consent process will you use?
- Are there incentives involved and if so what are the ethical issues around this?
- What ethics approval steps do you anticipate having to follow (include university, other institutional, community, etc) – **specific to the country or countries involved**
- Does your study have any sponsors? If so, are there any foreseen ethical conflicts regarding source of funding, support or sponsors, and potential results?
- What processes are in place for possible adverse events?



…. just 37 clauses

http://www.wma.net/en/30publications/10policies/b3/index.html

Council for International Organizations of Medical Sciences (CIOMS)



International Ethical Guidelines for Epidemiological Studies

Price: Swiss francs 45.–
Order from CIOMS,
c/o WHO, Avenue Appia 20,
CH–1211 Geneva 27, Switzerland.
E-mail: cioms@who.int
Tel. (+41 22) 791 34 13
Fax: (+41 22) 791 42 86

https://www.ufrgs.br/bioetica/cioms2008.pdf

http://pharmacoepi.org/world/index.cfm

International Society for Pharmacoepidemiology

http://pharmacoepi.org/world/index.cfm

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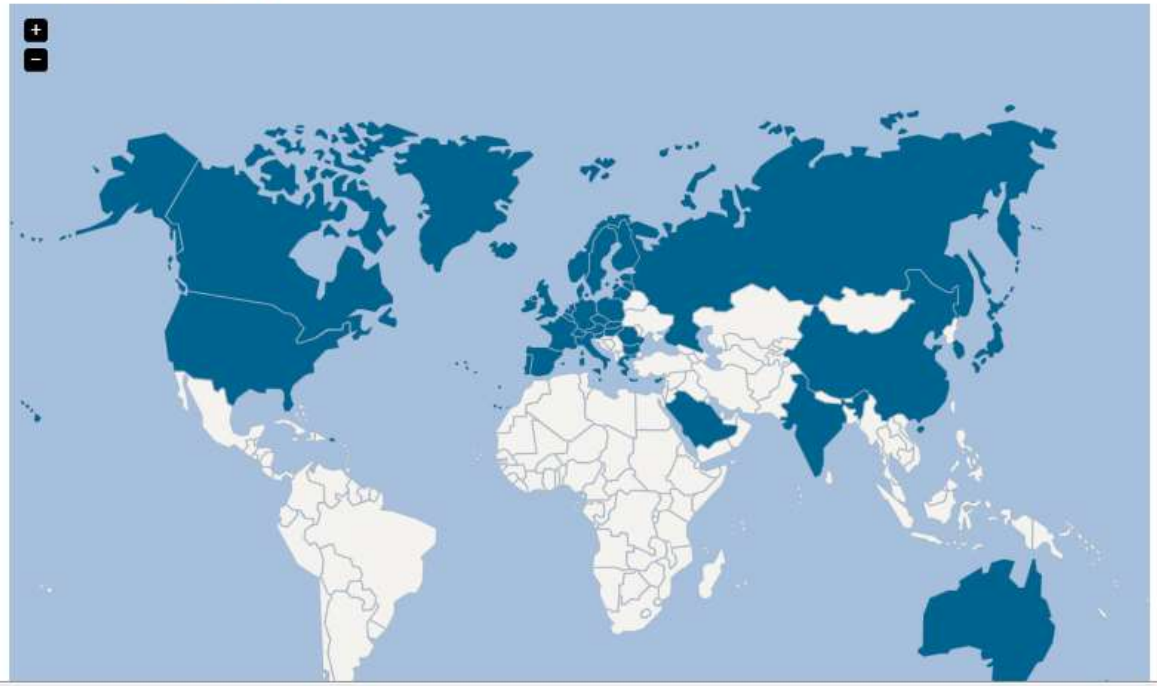
International Pharmacoepidemiology Legislation

The conduct of pharmacoepidemiology studies are regulated by pharmacovigilance legislation which varies by region and country throughout the globe. These regulations and resulting definitions and requirements are summarised in guidance documents for study sponsors and other individuals involved in study conduct. The International Society for Pharmacoepidemiology (ISPE) and the MAPI Research Trust (MRT) have teamed up to provide a central resource summarizing these regulatory guidelines for individual countries where guidance documents can be located. This is an on-going project, so if you have corrections or further information, please write to us at info@pharmacoepi.org.



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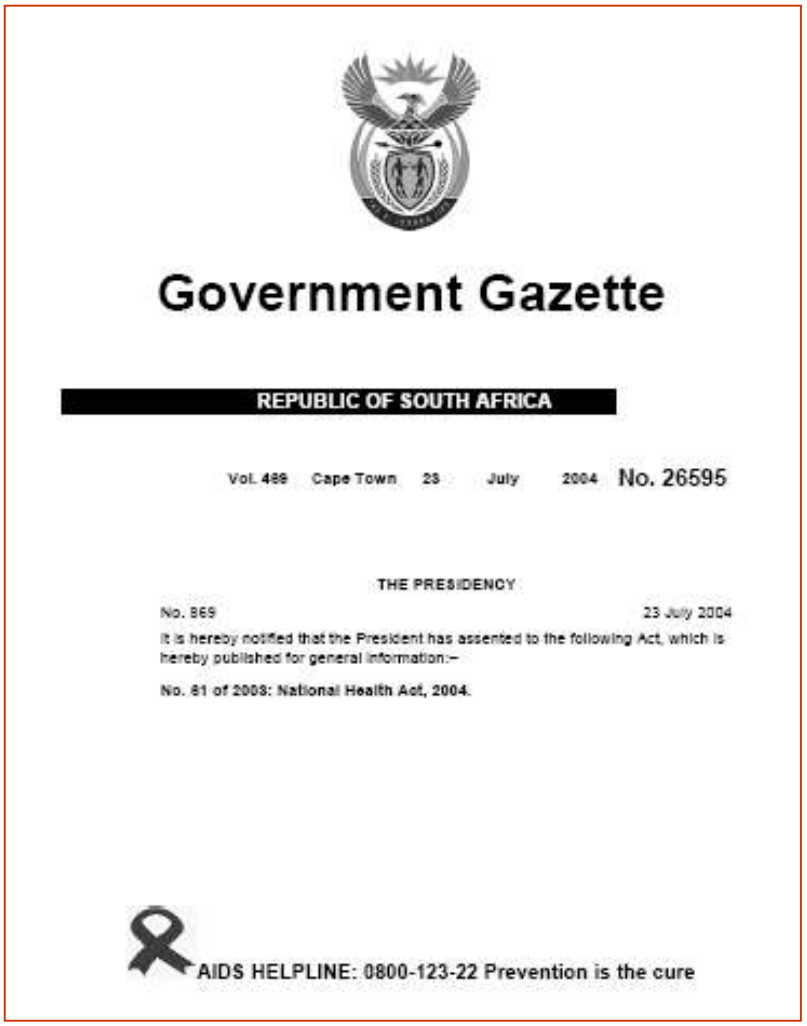
The legal backing in South Africa



Government Gazette

REPUBLIC OF SOUTH AFRICA

Vol. 469 Cape Town 23 July 2004 No. 26595

THE PRESIDENCY

No. 869 23 July 2004

It is hereby notified that the President has assented to the following Act, which is hereby published for general information:–

No. 61 of 2003: National Health Act, 2004.

AIDS HELPLINE: 0800-123-22 Prevention is the cure

73. (1) Every institution. health agency and health establishment at which health research is conducted, must establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Council.

Principles guiding research with human participants

Regulation 2. Health research that involves human participants must-

(a) comply with the Department of Health national ethical guidelines for research with human participants at a minimum;

(b) be responsive to health needs or priorities of the population, participating community or proposed participants;

(c) have a valid scientific methodology and be likely to provide answers for the specific research questions that are posed;

(d) include a favourable risk-benefit analysis;

(e) ensure that the recruitment and selection process is just and fair;

(f) be undertaken with appropriate consent processes;

(g) undergo independent review by a registered health research ethics committee;

(h) respect participants' rights, including but not limited to rights to dignity, privacy, bodily integrity and equality;

(i) make provision for compensation for research-related injury, for more than minimal risk research; and

(j) be managed by a lead researcher, or person with similar standing or title, with suitable experience and qualifications.

Confidentiality

National Health Act s14.

(1) All information concerning a user, including information relating to his or her health status, treatment or stay in a health establishment, is confidential.

(2) Subject to section 15, no person may disclose any information contemplated in sub-section (1) unless-

(a) the user consents to that disclosure in writing;

(b) a court order or any law requires that disclosure; or

(c) non-disclosure of the information represents a serious threat to public health.

Access to health records

15. (1) A health worker or any health care provider that has access to the health records of a user may disclose such personal information to any other person, health care provider or health establishment as is necessary for any legitimate purpose within the ordinary course and scope of his or her duties where such access or disclosure is in the interests of the user.

(2) For the purpose of this section, “personal information” means personal information as defined in section 1 of the Promotion of Access to Information Act, 2000 (Act No. 2 of 2000).

Access for “study”

16. (1) A health care provider may examine a user’s health records for the purposes of-

(a) treatment with the authorisation of the user; and

(b) study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee.

(2) If the study, teaching or research contemplated in subsection (1)*(b)* reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisations contemplated in that subsection.

SA MRC 2004 guidelines

Data gathered for administrative purposes or audit does not require the participants' consent if obtaining the consent could cause undue concerns, be impractical or too expensive. However, where publication of audited results may have potentially adverse consequences for study participants or for particular social groups, consent to use such data must be sought. Researchers should always seek the advice of a research ethics committee to decide whether record review requires individual consent.

2004 guideline contd (2)

A research ethics committee may approve the collection of data from records, either retrospectively or prospectively, that is identified or potentially identifiable if:

- It is satisfied that the scientific validity of the study would be compromised by de-identifying the data (i.e. that the objectives of the study could not be attained by de-identifying the data), or that
- An alternative study design which allowed for the use of de-identified data to meet the same objective was not possible, and that confidentiality of data collected could be assured.

2004 guideline contd (2)

Where data is collected from records, either retrospectively or prospectively, a research ethics committee may approve access to identified or potentially identifiable data without seeking the consent of those whom the data identifies, where the ethics committee is satisfied that:

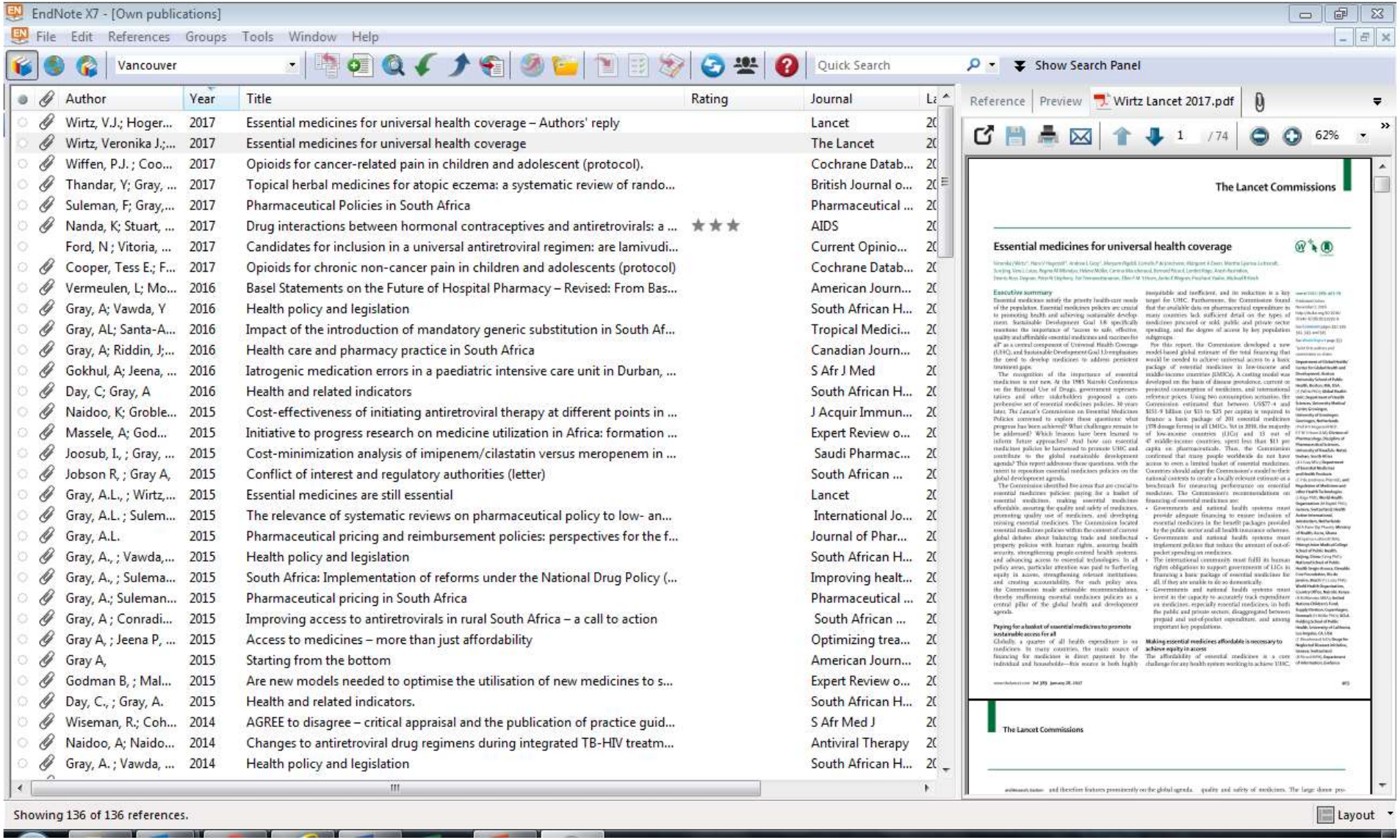
- The procedures required to obtain consent are likely either:
  - to cause unnecessary anxiety for those whose consent would be sought; or
  - to prejudice the scientific value of the research;
- There will be no disadvantage to the participants, their relatives or any collectivity involved that will compromise their rights and dignity to an extent unreasonable and unjustified in terms of the benefits of the research;
- It is impossible in practice, due to the quantity, age or accessibility of the records to be studied, to obtain consent; and public interest in the research outweighs to a substantial degree the public interest in privacy.

Dissemination

- How will you make sure people know about your results?
  - Who are relevant stakeholders?
  - What steps or techniques will you use to disseminate the results of your work?
  - How will participants be informed about the information from the study?

References

- Be consistent with use of references
  - Harvard
  - Vancouver
- Reference manager
  - Mendeley
  - Endnote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Essential medicines for universal health coverage
Executive summary
The Lancet Commissions
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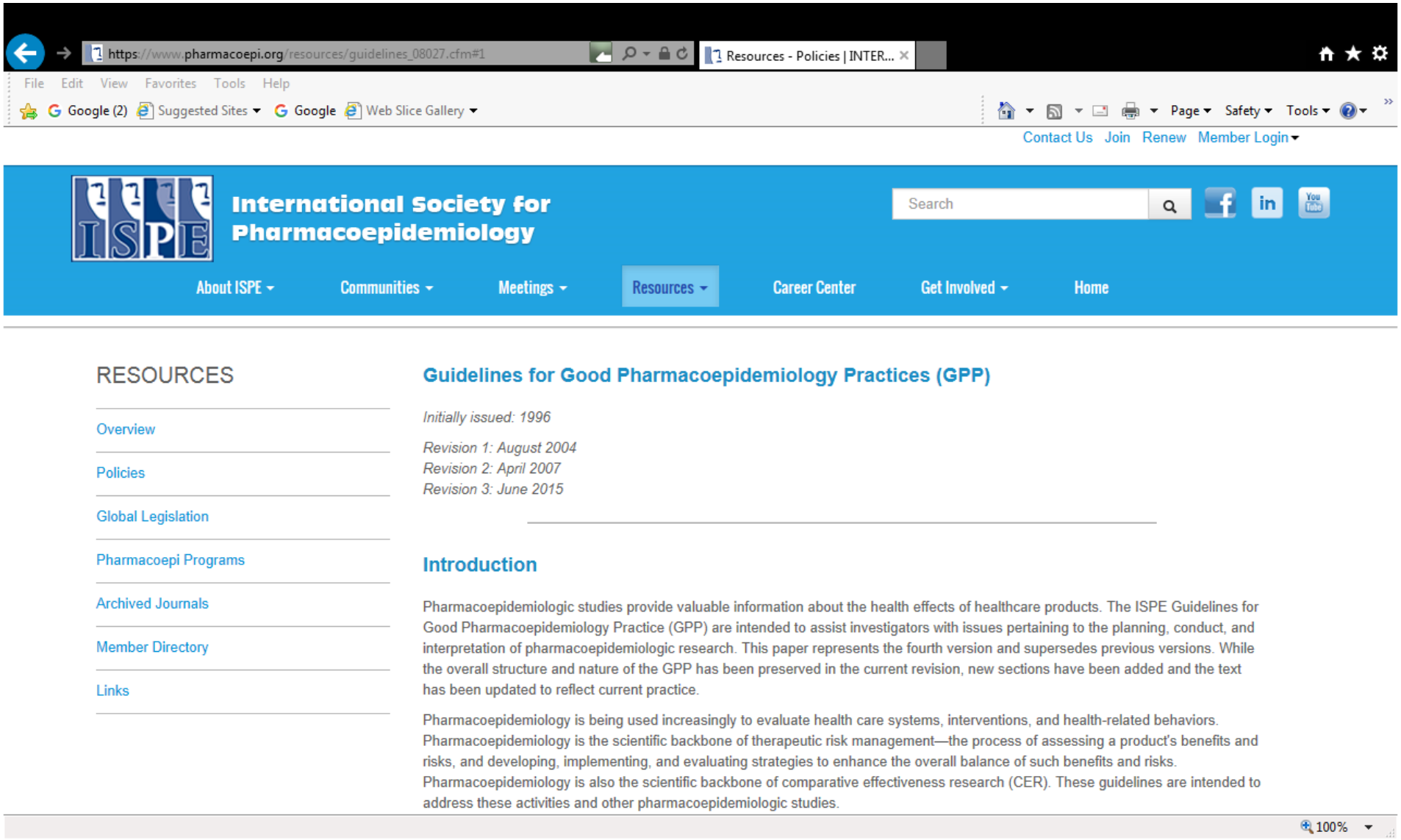
Layout

Appendices

- Provide draft data collection instruments
- Include examples of consent forms, if applicable to your study

https://www.pharmacoepi.org/resources/guidelines_08027.cfm#1



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

Doc.Ref. EMA/540136/2009

ENCePP Checklist for Study Protocols (Revision 2, amended)

Adopted by the ENCePP Steering Group on 14/01/2013

Study title:

Study reference number:

Section 1: Milestones	**Yes**	**No**	**N/A**	**Page Number(s)**
1.1 Does the protocol specify timelines for				
1.1.1 Start of data collection[1]	☐	☐	☐	
1.1.2 End of data collection[2]	☐	☐	☐	
1.1.3 Study progress report(s)	☐	☐	☐	
1.1.4 Interim progress report(s)	☐	☐	☐	
1.1.5 Registration in the EU PAS register	☐	☐	☐	
1.1.6 Final report of study results.	☐	☐	☐	

Comments:

Section 2: Research question	**Yes**	**No**	**N/A**	**Page Number(s)**
2.1 Does the formulation of the research question and objectives clearly explain:				
2.1.1 Why the study is conducted? (e.g. to address an important public health concern, a risk identified in the risk management plan, an emerging safety issue)	☐	☐	☐	
2.1.2 The objective(s) of the study?	☐	☐	☐	
2.1.3 The target population? (i.e. population or subgroup to whom the study results are intended to be generalised)	☐	☐	☐	
2.1.4 Which formal hypothesis(-es) is (are) to be tested?	☐	☐	☐	
2.1.5 If applicable, that there is no *a priori* hypothesis?	☐	☐	☐	

Comments:

Section 3: Study design	**Yes**	**No**	**N/A**	**Page Number(s)**
3.1 Is the study design described? (e.g. cohort, case-control, randomised controlled trial, new or alternative design)	☐	☐	☐	
3.2 Does the protocol specify the primary and secondary (if applicable) endpoint(s) to be investigated?	☐	☐	☐	
3.3 Does the protocol describe the measure(s) of effect? (e.g. relative risk, odds ratio, deaths per 1000 person-years, absolute risk, excess risk, incidence rate ratio, hazard ratio, number needed to harm (NNH) per year)	☐	☐	☐	

Comments:

Section 4: Source and study populations	**Yes**	**No**	**N/A**	**Page Number(s)**
4.1 Is the source population described?	☐	☐	☐	
4.2 Is the planned study population defined in terms of:				
4.2.1 Study time period?	☐	☐	☐	
4.2.2 Age and sex?	☐	☐	☐	
4.2.3 Country of origin?	☐	☐	☐	
4.2.4 Disease/indication?	☐	☐	☐	
4.2.5 Co-morbidity?	☐	☐	☐	
4.2.6 Seasonality?	☐	☐	☐	
4.3 Does the protocol define how the study population will be sampled from the source population? (e.g. event or inclusion/exclusion criteria)	☐	☐	☐	

Comments:

Section 5: Exposure definition and measurement	**Yes**	**No**	**N/A**	**Page Number(s)**
5.1 Does the protocol describe how exposure is defined and measured? (e.g. operational details for defining and categorising exposure)	☐	☐	☐	
5.2 Does the protocol discuss the validity of exposure measurement? (e.g. precision, accuracy, prospective ascertainment, exposure information recorded before the outcome occurred, use of validation sub-study)	☐	☐	☐	
5.3 Is exposure classified according to time windows? (e.g. current user, former user, non-use)	☐	☐	☐	
5.4 Is exposure classified based on biological mechanism of action and taking into account the pharmacokinetics and pharmacodynamics of the drug?	☐	☐	☐	
5.5 Does the protocol specify whether a dose-dependent or duration-dependent response is measured?	☐	☐	☐	

Comments:

Section 6: Endpoint definition and measurement	**Yes**	**No**	**N/A**	**Page Number(s)**
6.1 Does the protocol describe how the endpoints are defined and measured?	☐	☐	☐	
6.2 Does the protocol discuss the validity of endpoint measurement? (e.g. precision, accuracy, sensitivity, specificity, positive predictive value, prospective or retrospective ascertainment, use of validation sub-study)	☐	☐	☐	

Comments:

Section 7: Confounders and effect modifiers	**Yes**	**No**	**N/A**	**Page Number(s)**
7.1 Does the protocol address known confounders? (e.g. collection of data on known confounders, methods of controlling for known confounders)	☐	☐	☐	
7.2 Does the protocol address known effect modifiers? (e.g. collection of data on known effect modifiers, anticipated direction of effect)	☐	☐	☐	

Comments:

Section 8: Data sources	Yes	No	N/A	Page Number(s)
8.1 Does the protocol describe the data source(s) used in the study for the ascertainment of:				
8.1.1 Exposure? (e.g. pharmacy dispensing, general practice prescribing, claims data, self-report, face-to-face interview, etc.)	☐	☐	☐	
8.1.2 Endpoints? (e.g. clinical records, laboratory markers or values, claims data, self-report, patient interview including scales and questionnaires, vital statistics, etc.)	☐	☐	☐	
8.1.3 Covariates?	☐	☐	☐	
8.2 Does the protocol describe the information available from the data source(s) on:				
8.2.1 Exposure? (e.g. date of dispensing, drug quantity, dose, number of days of supply prescription, daily dosage, prescriber)	☐	☐	☐	
8.2.2 Endpoints? (e.g. date of occurrence, multiple event, severity measures related to event)	☐	☐	☐	
8.2.3 Covariates? (e.g. age, sex, clinical and drug use history, co-morbidity, co-medications, life style, etc.)	☐	☐	☐	
8.3 Is a coding system described for:				
8.3.1 Diseases? (e.g. International Classification of Diseases (ICD)-10)	☐	☐	☐	
8.3.2 Endpoints? (e.g. Medical Dictionary for Regulatory Activities (MedDRA) for adverse events)	☐	☐	☐	
8.3.3 Exposure? (e.g. WHO Drug Dictionary, Anatomical Therapeutic Chemical (ATC)Classification System)	☐	☐	☐	
8.4 Is the linkage method between data sources described? (e.g. based on a unique identifier or other)	☐	☐	☐	

Section 9: Study size and power	**Yes**	**No**	**N/A**	**Page Number(s)**
9.1 Is sample size and/or statistical power calculated?	☐	☐	☐	

Comments:

Section 10: Analysis plan	**Yes**	**No**	**N/A**	**Page Number(s)**
10.1 Does the plan include measurement of excess risks?	☐	☐	☐	
10.2 Is the choice of statistical techniques described?	☐	☐	☐	
10.3 Are descriptive analyses included?	☐	☐	☐	
10.4 Are stratified analyses included?	☐	☐	☐	
10.5 Does the plan describe methods for adjusting for confounding?	☐	☐	☐	
10.6 Does the plan describe methods addressing effect modification?	☐	☐	☐	

Section 11: Data management and quality control	**Yes**	**No**	**N/A**	**Page Number(s)**
11.1 Is information provided on the management of missing data?	☐	☐	☐	
11.2 Does the protocol provide information on data storage? (e.g. software and IT environment, database maintenance and anti-fraud protection, archiving)	☐	☐	☐	
11.3 Are methods of quality assurance described?	☐	☐	☐	
11.4 Does the protocol describe possible quality issues related to the data source(s)?	☐	☐	☐	
11.5 Is there a system in place for independent review of study results?	☐	☐	☐	

Comments:

Section 12: Limitations	**Yes**	**No**	**N/A**	**Page Number(s)**
12.1 Does the protocol discuss: 12.1.1 Selection biases? 12.1.2 Information biases? (e.g. anticipated direction and magnitude of such biases, validation sub-study, use of validation and external data, analytical methods)	☐ ☐	☐ ☐	☐ ☐	
12.2 Does the protocol discuss study feasibility? (e.g. sample size, anticipated exposure, duration of follow-up in a cohort study, patient recruitment)	☐	☐	☐	
12.3 Does the protocol address other limitations?	☐	☐	☐	

Comments:

Section 13: Ethical issues	**Yes**	**No**	**N/A**	**Page Number(s)**
13.1 Have requirements of Ethics Committee/Institutional Review Board approval been described?	☐	☐	☐	
13.2 Has any outcome of an ethical review procedure been addressed?	☐	☐	☐	
13.3 Have data protection requirements been described?	☐	☐	☐	

Comments:

Section 14: Amendments and deviations	**Yes**	**No**	**N/A**	**Page Number(s)**
14.1 Does the protocol include a section to document future amendments and deviations?	☐	☐	☐	

Section 15: Plans for communication of study results	**Yes**	**No**	**N/A**	**Page Number(s)**
15.1 Are plans described for communicating study results (e.g. to regulatory authorities)?	☐	☐	☐	
15.2 Are plans described for disseminating study results externally, including publication?	☐	☐	☐	

Comments:

Name of the main author of the protocol: _____

Date: / /

Signature: _____

Just do it!


The Research Process
Initiate
What do I really need to find out?
Locate
How do I find the information?
Select
What information is relevant and reliable?
Organise
How can I use this information?
Present
How can I communicate my research?
Assess
What did I learn from this process?