

Optimal treatment for patients with solid tumours in Europe through Artificial Intelligence

D3.1: A report on identified research questions and guidelines, including process of selection and prioritisation



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1. Abstract

Bringing clinical data together with the aim of addressing knowledge gaps requires a thorough process of identification and prioritisation of these knowledge gaps. It is important to include all relevant stakeholders in this process. This deliverable describes the methods and results used to come to OPTIMA's list of prioritised knowledge gaps for breast, lung, and prostate cancers. In addition, it describes the identification, grading (AGREE II assessment) and prioritisation of national and international breast, lung, and prostate cancer guidelines. This will form the basis for development of OPTIMA's Guideline Based Decision Support Tool (GBDST).

2. Methods

WP₃ has, from the start of OPTIMA, initiated weekly meetings with both the WP leads from Academia and Pharma (N=3; EMC, SR, Roche) and the management group of WP₃ (WP leads including lead scientists (N=7; EMC, SR, UofA, Roche). Meetings with all partners working in WP₃ or connected through other WPs are scheduled at a monthly basis.

Identification and prioritisation of critical research questions

A detailed description of the method of identification and prioritisation of prostate cancer research questions (RQs) is recently published in Nature Reviews Urology. This work is carried out within the PIONEER consortium (<https://prostate-pioneer.eu/>). As described in the grant application of OPTIMA, a similar approach was chosen for identifying and prioritising breast and lung cancer RQs.

Please find below a short description of the method applied across all three cancer types:

The two most important stakeholder groups, for identifying the top unanswered questions in cancer, are healthcare professionals including doctors, researchers, and representatives from pharmaceutical companies. They are medically qualified and work in either research and development or medical affairs branches of industry (excluding people from marketing departments (HCPs)). These Stakeholders design and administer care and drive the research agenda. Moreover, since the patient groups are the recipients of the benefits and harms of care and research, they are key contributors. The modified Delphi method was identified as appropriate to assess agreement within and between these stakeholder groups, and to facilitate consensus. The modified Delphi method allows for anonymous controlled feedback, whereby participants are first asked to score a series of items, then, in subsequent rounds are shown a summary of the scores that other participants attributed to each item in the previous round. They are then asked to re-score the items.

For prostate cancer the European Urology Association (EAU) Prostate Cancer Guideline panel and other prostate cancer Key Opinion Leaders were consulted to propose the most critical questions in the field of prostate cancer to be answered using big data. Through this process, 44 key questions were identified. Afterwards, the PIONEER consortium conducted a two-round modified Delphi survey in order to assess and build consensus between the two stakeholder groups: healthcare professionals (including representatives from pharmaceutical companies) and prostate cancer patients. Respondents were asked to consider what impact answering the proposed questions would have on better diagnosis and treatment outcomes for prostate cancer, while scoring these questions on a scale of 1 (not important) to 9 (critically important). The results were analysed by calculating the percentage of respondents scoring each question as: not important (score 1 to 3), important (score 4 to 6) or critically important (score 7 to 9). In the second round, participants were shown a summary of the percentage of other participants (patients and healthcare professionals) who considered the question "critically important" in round one.

For a detailed description we would like to refer to :

Unanswered questions in prostate cancer: Findings of an international multi-stakeholder consensus by the PIONEER Consortium Authors: Muhammad Imran Omar, Steven MacLennan, Maria J Ribal, Monique J Roobol, Konstantinos Dimitropoulos, Thomas van den Broeck, Sara MacLennan, Susan Evans Axelsson, Giorgio Gandaglia, Peter-Paul Willemse, Ken Mastris, John-Edward Butler-Ransohoff, Zsuzsanna Devecséri, Thomas Abbott, Bertrand De Meulder, Anders Bjartell, Alex Asiimwe, and James N'Dow

Reference to publication: Omar, M.I., MacLennan, S., Ribal, M.J. et al. Unanswered questions in prostate cancer — findings of an international multi-stakeholder consensus by the PIONEER consortium. *Nat Rev Urol* (2023). <https://doi.org/10.1038/s41585-023-00748-9>

Breast cancer questions were sourced in 2022 by liaising with relevant organizations that were suggested during the 2022 March 1st WP3 meeting and/or already identified during grant writing. Organisations involved in the first stage of development of RQs were ASCO, ESTRO, AIOM, Breast Cancer Now, IKNL, KCE, ICO, IEO, EUBREAST, Europa Donna, ESR, ECO, and ESMO.

Initial streamlining and prioritisation were performed by the following organisations representing both HCP and patients: WP3 team, ESTRO, ECO, Breast cancer Now, ICO, Europa Donna. In addition, through an internal OPTIMA survey potential critical RQs were received from OPTIMA's breast cancer clinical content expert and pharma. Finally, a rapid review of the evidence was performed, and extracted themes and research questions were added to the survey.

Lung Cancer: Similar to breast cancer, relevant stakeholders were consulted, and an OPTIMA internal survey was done, completed by a rapid review. All of the questions and priorities were compiled and reviewed by relevant clinicians, patients, and researchers and reformatted. Organisations involved were ELF (patient organisation), ERS, ASCO, ESTRO, ICO, ECO, IKNL, British Thoracic Society, American thoracic Society, Lung cancer expert group, Roy castle Lung cancer Foundation, Lung cancer Nursing UK and Pfizer.

Guidelines identification, AGREE II assessment and prioritisation.

The bulk of the work has been carried out during grant writing. Please find below (Result section) the tables that were part of the grant proposal.

Prostate cancer: building further on PIONEER and the work done during OPTIMA grant writing, no additional guidelines were included. Identification of CPGs was done through our network as well as a consensus during a prioritisation meeting with participants in WP3, patients and pharma partners. These CPGs were assessed using the AGREE II tool. Results can be found in the result section.

Breast cancer: next to the CPGs that were identified and graded during grant writing, we asked the breast cancer clinical leads to identify additional CPGs that should be included in our AGREE II assessment and prioritisation exercise. These guidelines were assessed, and details can be found in the results section. However, to identify which CPGs are used most frequently in clinical practice and why these are used, we have developed a survey. The survey will be shared by the breast cancer clinical leads with their network as well as via the OPTIMA network. Following a similar approach as in prostate cancer, the consensus on the identified CPGs will be established with input from the network and the assessed CPGs.

Lung cancer: For lung cancer, we followed a different approach due to the high number and diversity of available guidelines, we shared a survey among the members of the OPTIMA consortium and the network of the lung cancer leads, with the aim to identify the most frequently used lung cancer guidelines and why these are used, as a first step. The identified guidelines were added to the already AGREE II assessed guidelines. Prioritisation was planned according to the prostate and breast cancer procedure.

4. Results

Minutes of WP leads meetings can be found at:

<https://ttopstart365.sharepoint.com/sites/IMI-23OptimaltreatmentAlforsolidtumours/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2FIMI%2D23OptimaltreatmentAlforsolidtumours%2FShared%20Documents%2FWP3%2DGuideline%2Dbased%20decision%20support%20tool%2FWP%20lead%20Meeting%20Minutes&viewid=c03c6817%2D8dc7%2D46da%2D8283%2Da0c3573a8ddd>

Small group meetings

[https://ttopstart365.sharepoint.com/:f:/r/sites/IMI-23OptimaltreatmentAlforsolidtumours/Shared%20Documents/WP3-Guideline-based%20decision%20support%20tool/Small%20Group%20\(Task%201,2.3\)%20meeting%20minutes?csf=1&web=1&e=kdUlsj](https://ttopstart365.sharepoint.com/:f:/r/sites/IMI-23OptimaltreatmentAlforsolidtumours/Shared%20Documents/WP3-Guideline-based%20decision%20support%20tool/Small%20Group%20(Task%201,2.3)%20meeting%20minutes?csf=1&web=1&e=kdUlsj)

Identification and prioritisation of critical research questions

Prostate Cancer: We would like to refer to the recently published manuscript:

Unanswered questions in prostate cancer: Findings of an international multi-stakeholder consensus by the PIONEER Consortium Authors: Muhammad Imran Omar, Steven MacLennan, Maria J Ribal, Monique J Roobol, Konstantinos Dimitropoulos, Thomas van den Broeck, Sara MacLennan, Susan Evans Axelsson, Giorgio Gandaglia, Peter-Paul Willemse, Ken Mastris, John-Edward Butler-Ransohoff, Zsuzsanna Devcseri, Thomas Abbott, Bertrand De Meulder, Anders Bjartell, Alex Asiimwe, and James N'Dow

We initially had 144 questions. These included not only from the stakeholders but also from our literature search. There was considerable overlap and after streamlining we included 68 question in round 1. A total of 56 RQs have been identified and prioritised after round 2.

Breast cancer

Initially, we identified 128 questions via the network and the rapid systematic review. These have been standardised and we included 68 questions in the first round of the Delphi survey. The questions were translated into French, German, Spanish, and Italian to enable wide participation. The Delphi survey was shared on the 12th of January across the OPTIMA consortium together with a request, if applicable to disseminate the survey within their wider networks. After two rounds of reminders, we currently have 48 responses across stakeholder groups (patients, HCPs and Consortium members)

Lung cancer

Initially, we identified 55 research questions through internal consultation and the rapid systematic review. These have been standardised and we included 52 research questions in the first round of the Delphi survey. The questions were translated into French, German, Spanish, and Italian to enable wide participation. The first round of the Delphi surveys for lung cancer RQs was shared on the 12th of January across the OPTIMA consortium together with a request, if applicable to disseminate the survey within their wider networks. After two rounds of reminders, we currently have 86 responses.

The second round of the Delphi was initiated in April after which we expect to finalise the identification and prioritisation of RQs for both breast and lung cancer in October 2023.

Guidelines identification, AGREE II assessment and prioritisation.

Prostate cancer

Table 1.2: Assessment of the prostate cancer guidelines using AGREE II tool

Domains (maximum score)	Prostate Cancer															
	AFU	ASC O (1)	ASC O (2)	ASC O (3)	ASC O (4)	AUA (1)	AUA (2)	EAU	ESMO	IKNL	KCE (1)	KCE (2)	NCCN	NICE	PNV (SE)	S3 (DE)
Scope and Purpose (21)	14	21	21	21	21	18	19	20	8	20	19	19	12	21	21	21
Stakeholder Involvement (21)	14	21	16	17	21	19	19	20	9	16	16	20	18	20	21	21
Rigour of Development (56)	50	46	42	43	49	49	52	56	23	41	52	56	38	54	34	51
Clarity of Presentation (21)	21	21	21	21	21	18	19	20	12	19	21	21	20	21	21	20
Applicability (28)	17	6	8	19	17	22	21	20	12	19	23	26	26	23	26	22
Editorial Independence (14)	14	14	14	14	14	14	14	14	10	11	14	14	12	13	14	14
Overall Assessment	6/7	6/7	6/7	6/7	6/7	4/7	4/7	7/7	4/7	6/7	5/7	6/7	6/7	7/7	6/7	7/7

We are currently updating the AGREE II assessments to ensure the latest CPG updates are captured. Moreover, to ensure interrater reliability, we are assessing the updated CPGs in duplicate. At the general assembly meeting of OPTIMA, we will discuss and prioritise the CPGs based on input from all stakeholders.

Breast cancer

Table 1.1: Assessment of the breast cancer guidelines using AGREE II tool

Domains (maximum score)	Breast cancer										
	AGO	AIOM	ASCO	ESMO	IKNL	KCE	La HAS	NCCN	NICE	SIGN	
Scope and Purpose (21)	3	19	20	21	19	18	10	15	16	16	
Stakeholder Involvement (21)	4	16	19	16	18	16	4	12	17	17	
Rigour of Development (56)	21	43	50	47	44	46	24	40	43	43	
Clarity of Presentation (21)	14	18	19	21	19	16	20	21	17	17	
Applicability (28)	4	23	23	14	17	24	10	18	23	23	
Editorial Independence (14)	2	14	12	14	14	11	2	11	12	12	

In 2022, we asked breast cancer clinical leads to identify any other new guidelines they think should be assessed and 10 more CPGs were identified for assessment. These are:

- European Breast guidelines on Breast Cancer Screening and Diagnosis (<https://healthcare-quality.jrc.ec.europa.eu/ecibc/european-breast-cancer-guidelines>) –
- German guideline (DE) (<https://www.leitlinienprogramm-onkologie.de/leitlinien/mammakarzinom/>) – 2 appraisers
- Risk reduction and screening of cancer in hereditary breast-ovarian cancer syndromes: ESMO Clinical Practice Guideline ([https://www.annalsofncology.org/action/showPdf?pii=S0923-7534\(22\)04193-X](https://www.annalsofncology.org/action/showPdf?pii=S0923-7534(22)04193-X))
- ESMO Clinical Practice Guideline for the diagnosis, staging and treatment of patients with metastatic breast cancer ([https://www.annalsofncology.org/article/S0923-7534\(21\)04498-7/fulltext](https://www.annalsofncology.org/article/S0923-7534(21)04498-7/fulltext))
- Use of Immune Checkpoint Inhibitors in the Treatment of High-Risk, Early-Stage Triple-Negative Breast Cancer: ASCO Guideline Rapid Recommendation Update Q and A (<https://ascopubs.org/doi/pdf/10.1200/OP.22.00284?role=tab>), Use of Immune Checkpoint Inhibitor Pembrolizumab in the Treatment of High-Risk, Early-Stage Triple-Negative Breast Cancer: ASCO Guideline Rapid Recommendation Update (https://ascopubs.org/doi/10.1200/JCO.22.00503?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=fmetastaticcr_pub%20%20pubmed) in conjunction with the

original guideline Neoadjuvant Chemotherapy, Endocrine Therapy, and Targeted Therapy for Breast Cancer: ASCO Guideline: <https://ascopubs.org/doi/full/10.1200/JCO.20.03399>

- Endocrine Treatment and Targeted Therapy for Hormone Receptor-Positive, Human Epidermal Growth Factor Receptor 2-Negative Metastatic Breast Cancer: ASCO Guideline Update (Endocrine Treatment and Targeted Therapy for Hormone Receptor–Positive, Human Epidermal Growth Factor Receptor 2–Negative Metastatic Breast Cancer: ASCO Guideline Update | Journal of Clinical Oncology (ascopubs.org))
- Systemic Therapy for Advanced Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer: ASCO Guideline Update (https://ascopubs.org/doi/10.1200/JCO.22.00519?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed)
- Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer: ASCO Guideline Update (<https://ascopubs.org/doi/full/10.1200/JCO.22.00069>)
- Management of Advanced Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer and Brain Metastases: ASCO Guideline Update (<https://ascopubs.org/doi/pdf/10.1200/JCO.22.00520?role=tab>) in conjunction with the original guideline
- Adjuvant Abemaciclib Plus Endocrine Therapy in the Treatment of High-Risk Early Breast Cancer: ASCO Guideline Rapid Recommendation Update Q and A (https://ascopubs.org/doi/10.1200/OP.22.00140?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed) in conjunction with the guideline Adjuvant Abemaciclib Plus Endocrine Therapy in the Treatment of High-Risk Early Breast Cancer: ASCO Guideline Rapid Recommendation Update Q and A and Selection of Optimal Adjuvant Chemotherapy and Targeted Therapy for Early Breast Cancer: ASCO Guideline Update

The results of the AGREE II assessment are listed below.

Domains (maximum score)	Appraised in 2022-2023								
	DE	ESMO risk reduction	ESMO metastatic	ASCO early BC	ASCO neoadjuvant	ASCO brain mets	ASCO biomarkers	ASCO metastatic	ASCO HER2+
Scope and Purpose (21)	12/17	19	17	19	21	19	21	21	21
Stakeholder Involvement (21)	19/18	13	14	13	18	14	18	19	18
Rigour of Development (56)	47/53	45	43	31	53	48	53	49	55
Clarity of Presentation (21)	16/19	19	20	18	19	21	20	20	20
Applicability (28)	18/18	19	20	8	27	14	23	21	24
Editorial Independence (14)	11/11	14	13	6	12	11	9	13	13
Overall Assessment	5/7/6/7	6/7	6/7	5/7	7/7	6/7	6/7	5/7	6/7

This work will be extended, as we are currently designing a survey similar to Lung Cancer, to highlight which CPGs are used most commonly in clinical practice and the reason why these guidelines are used. This will inform final prioritisation of the CPGs.

Lung cancer

Table 1.3: Assessment of the lung cancer guidelines using AGREE II tool

Domains (maximum score)	Lung cancer														
	ESMO (1)	ESMO (2)	ESMO (3)	GL (FR)	S3 (DE)	NICE	NSCLC (CZ)	SCLC (CZ)	GL (DK)	FM (NL)	GL (N)	SEOM NSCLC (ES)	SEOM SCLC (ES)	GL (S)	AIOM (I)
Scope and Purpose (21)	17	16	14	14	21	19	13	10	17	14	12	13	13	17	18
Stakeholder Involvement (21)	12	12	11	10	18	21	13	12	14	14	14	14	14	14	17
Rigour of Development (56)	36	32	31	34	47	52	32	36	40	34	39	30	29	37	47
Clarity of Presentation (21)	19	17	16	21	18	21	13	14	16	13	16	11	11	14	16
Applicability (28)	8	8	8	14	21	27	18	18	21	17	27	13	12	19	21
Editorial Independence (14)	8	8	8	12	13	13	9	12	11	10	10	10	10	10	12
Overall Assessment	5/7	5/7	5/7	6/7	6/7	7/7	4/7	4/7	5/7	5/7	5/7	4/7	4/7	5/7	6/7

As part of the assessment of the lung cancer guidelines, we performed a survey which tries to identify, which guidelines are most commonly used across the EU and why these CPGs are used.

The survey is still open and until now 15 HCPs (87% are at consultant level and 13% junior doctors) responded. Across the stages, the NICE guidelines seem to be the most commonly used guidelines, as indicated by the participants. These were chosen predominantly due to the comprehensiveness and methodology of the guidelines. More details are presented below.

LDCT-Screening for Lung Cancer/Workup of pulmonary nodules (either incidental or screen-detected):
<ul style="list-style-type: none"> National Comprehensive Cancer Network (NCCN, UK): Lung Cancer Screening (3, 21,4%) British Thoracic Society (BTS, UK): Guidelines for the Investigation and Management of Pulmonary Nodules (14 (100%)) European position statement on lung cancer screening (1, 7.1%) "Other" (1, 7.1%)
Diagnostics for lung cancer
<ul style="list-style-type: none"> ERS/ESTS: Clinical guidelines on fitness for radical therapy in lung cancer patients (surgery and chemoradiotherapy) (1, 7,1%) National Comprehensive Cancer Network (NCCN, USA): Non-Small Cell Lung Cancer (1, 7,1%) National Institute for Health and Care Excellence (NICE, UK): Lung cancer: diagnosis and management (14, 100,0%) Other (2, 14,3%)
Early stage non-small cell lung cancer
<ul style="list-style-type: none"> American Society of Clinical Oncology (ASCO, USA): Adjuvant Chemotherapy and Adjuvant Radiation Therapy for Stages I-IIIa Resectable Non-Small Cell Lung Cancer (1, 6,7%) European Society for Medical Oncology (ESMO): Early-Stage and Locally Advanced (non-metastatic) Non-Small-Cell Lung Cancer (3, 20,0%) National Comprehensive Cancer Network (NCCN, USA): Non-Small Cell Lung Cancer (1, 6,7%) National Institute for Health and Care Excellence (NICE, UK): Lung cancer: diagnosis and management (15, 100,0%) Other (1, 6,7%)
Locally advanced non-small cell lung cancer
<ul style="list-style-type: none"> American Society of Clinical Oncology (ASCO, USA): Management of Stage III Non-Small Cell Lung Cancer (2, 13,3%) European Society for Medical Oncology (ESMO): Early-Stage and Locally Advanced (non-metastatic) Non-Small-Cell Lung Cancer (4, 26,7%) National Comprehensive Cancer Network (NCCN, USA): Non-Small Cell Lung Cancer (1, 6,7%) National Institute for Health and Care Excellence (NICE, UK): Lung cancer: diagnosis and management (15, 100,0%) Other (1, 6,7%)
Metastatic non-small cell lung cancer
<ul style="list-style-type: none"> American Society of Clinical Oncology (ASCO, USA): Therapy for Stage IV Non-Small Cell Lung Cancer without Driver Alterations Living Guideline (1, 6,7%) American Society of Clinical Oncology (ASCO, USA): Therapy for Stage IV Non-Small Cell Lung Cancer with Driver Alterations Living Guideline (1, 6,7%) European Society for Medical Oncology (ESMO) Metastatic Non-Small-Cell Lung Cancer (5, 33,3%) National Comprehensive Cancer Network (NCCN, USA): Non-Small Cell Lung Cancer (1, 6,7%) National Institute for Health and Care Excellence (NICE, UK): Lung cancer: diagnosis and management (15, 100,0%) Other (1, 6,7%)
Small cell lung cancer
<ul style="list-style-type: none"> European Society for Medical Oncology (ESMO): Small-Cell Lung Cancer (4, 26,7%) National Comprehensive Cancer Network (NCCN, USA): Small Cell Lung Cancer (1, 6,7%) National Institute for Health and Care Excellence (NICE, UK): Lung cancer: diagnosis and management (15, 100,0%)
Patient guidelines
<ul style="list-style-type: none"> Two participants highlight that there is a patient guideline which is used in their country, seven are not aware of a patient guideline and six report that there is no patient guideline.

For both breast and lung cancer prioritisation will be discussed during the general assembly meeting.

5. Discussion and Conclusion

This report describes deliverable 3.1 related to the identification and prioritisation of critical research questions and guidelines which will form the basis for the development and selection of care pathways and guideline-based recommendations, which at their turn will be the building stones for the GBDST. For Prostate cancer, having a considerable head start due to the sister project PIONEER, both the RQs and guidelines have been identified and are already used in the next phase of OPTIMA (cancer care pathways, GBDST and addressing RQs by use of the gathered data)

For breast and lung cancer, the road to accomplish this level has been challenging. The methodology used in PIONEER to identify and prioritise the RQS had to be discussed again and did not escape criticism, especially from a patient engagement point of view. It was stated that the survey was too lengthy, the questions were too complex and had too much medical terminology for patients to understand. Ideally, patient organisations would have preferred to have two surveys – one for HCP and pharma, and another – plain language one for patients. This was the initial methodology applied for prostate cancer in PIONEER, but learning from that process it was then decided that having a single survey would minimize the danger of loss of meaning between the medical and plain language questions. The solution chosen for PCa was that notes after each question were provided that explained the medical terminology. In addition, the questions most relevant to patients would be placed at the start of the survey.

Nevertheless, after a consultation after the first Delphi round with the PARB and ELF, it became clear that this approach was not optimal for breast and lung cancer patient representatives. After a joint meeting including methodologists it was agreed that there will be a separate survey in lay language for Delphi round 2. The PPAB and ELF teams will help in simplifying the language of the questions for both breast and lung cancer surveys. It was generally agreed and noted that it is essential that the context of the questions remains the same while streamlining in lay language, and ELF and PPAB members have ample experience in doing it. The adapted second round of Delphi will be available in the 3rd week of April 2023.

Similar to the RQS, also the identification of the prostate cancer guidelines profited from the sister project PIONEER. For breast and lung cancer, it turned out that the guideline landscape was more complex/diverse as compared to urology. This implied a lot more involvement of clinical leads and their networks to collect all relevant breast and lung cancer guidelines. Initially, lacking sufficient clinical support, the work has now a considerable delay. Fortunately, we have a complete overview of relevant guidelines of both cancer sites and the AGREE II assessments are finalised. This implies that the basis for further work in breast and lung cancer can continue without serious delays.

6. Repository for primary data

Breast cancer survey

<https://redcap.abdn.ac.uk/surveys/?s=9NX34MKDXE47ADMA>

Lung cancer survey

<https://redcap.abdn.ac.uk/surveys/?s=KEDR8X8LP8P8NXNW>

AGREE₂

<https://topstart365.sharepoint.com/:f:/r/sites/IMI-23OptimaltreatmentAlforsolidtumours/Shared%20Documents/WP3-Guideline-based%20decision%20support%20tool/Tasks%203.1,%203.2%20and%203.3/3.3%20-%20Agree2%20assessments?csf=1&web=1&e=7eMvwh>