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IJPAP

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Foreword to the First Edition

IJPAP. A new scientific journal. Another one? Do we need one? Don't we have enough already? Well maybe. Yet the editors do think there is still room for another one, particularly one that is dedicated to "pure and applied pharmacology". A journal focused on the action of drugs in the human body, on clinical research and on pharmaceutical patient care, medication adherence and pharmaceutical innovation. A wide variety of topics, indeed, with the ultimate aim of adding scientific evidence to drug therapy and of bringing new drug therapies to patients, of bridging the gap between innovative medication and the patients who might benefit from them.

The I in our name stands for International, because we also want to bridge another gap: that between the western world and the upcoming world. The APAP (Association for Pure and Applied Pharmacology) is a collaboration between scientists and universities in Europe and India. This collaboration is useful and needed because we believe that both worlds need each other, the 'old world' with an impressive track record of medical innovations, and the 'new world' which in the not too distant future will carry out much of the applied research and development in medication and patient care. Both worlds can benefit from each other and will establish synergy by working together.

We welcome any contributions in the abovementioned fields. Papers should be in accordance with the 'instructions to contributors' and will be reviewed by at least 2 referees. The eventual decision to publish will be made by the editorial board. The journal will appear on the web four times per year. It can be accessed at www.apapinternational.com

In addition to the 'official' journal, we will also edit a 'supplement'. This supplement is intended for contributions by students who, in the course of their studies, often have to deliver research results (practical, theoretical, literature searches etc.) that, despite giving them good grades, often disappear in a teacher's file without being used or referred to ever again. What a waste of effort and accumulated knowledge! By bringing abstracts of such student research work together in a web-based open access journal, it is hoped that the information is spread more broadly and that it will also lead to better international student communications. So again we welcome such contributions, within the same broad areas as the journal itself, and compliant with the aims and scope of the journal.

The APAP organizes an annual conference in Mumbai, India. Proceedings of this conference will also be included in the supplement. Any university lecturer or professor, either from Europe or India, who wishes to join in, is most welcome to contact the APAP - Prof. Dr. Dnynanesh Limaye (dnyanesh1in@gmail.com)

We hope and trust this new journal will supply in a definite want and we are looking forward to your reactions!

Prof. Dr. Ad van Dooren

Similarities and Differences between International Regulations in required Information for the Informed Consent Form: a comparison between ICH GCP and Code of Federal Regulations.

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Abstract

The purpose of this publication is to reveal similarities and differences between international Regulations in required information for the informed consent form. In detail the authors make a comparison between the two important documents regarding clinical trials of the European Union and the United States: the ICH Good Clinical Practice (GCP) and the Code of Federal Regulations (CFR). As a result a new global standard for required information for the informed consent form is developed.

Introduction

It was the author's intention to detect similarities and differences between international regulations in required information for the informed consent form. The focus was to examine the regulatory standards of the two big markets in the world: the United States and Europe, in order to fulfill the objective. Therefore the purpose was to compare ICH and FDA documents to discover existing similarities and differences.

The objective was to accomplish a detailed description of distinctions between the comprised standards in ICH GCP and Code of Federal Regulations for informed consent forms.

Furthermore, the question is whether a global standard can be found for drafting informed consent forms to conduct international trials in the European Union and the United States.

Methods and materials

To perform the comparison, the authors first acquired the respective regulations, meaning ICH Good Clinical Practice and Code of Federal Regulations of the FDA.

To obtain a better overview, the authors chose to create a table to clearly display irregularities and differences in the two documents. Also similarities have been detected using this method.

The concentration was a detailed comparison, going through both documents item by item. In this context all similarities have been color-coded as well as the differences. This result can be found in the annex.

The attention was not focused on the emphasis of points the ICH GCP and CFR have in common but to make the reader visualize distinctions which have been outlined afterwards.

In addition, a global standard for requirements of an informed consent form has been generated using the results of the previous comparison.

Results

The process of informed consent is described in ICH GCP in part "4.8 Informed Consent of Trial Subjects". The detailed list of its contents is integrated in section "4.8.10": it consists of 20 basic elements and five additional points.

In the case of Code of Federal Regulations (CFR) the topic informed consent is addressed in § 50.20 the "General requirements for informed consent" and in § 50.25 the "Elements of informed consent". These standards consist of eight basic and six additional elements.

In the following, attention is turned to the precise description of the differences between the two documents. Finally, a general guideline is presented that includes all important aspects of an informed consent that can be used to perform studies in the European Union and the United States at the same time. This developed global standard contains 22 basic elements and seven additional points to consider.

Differences between ICH GCP and CFR

The authors discovered many differences between the two documents.
The first difference is the ICH GCP requires the participant to be informed of the "trial treatments and the probability for random assignment to each treatment". The FDA Code of Regulations does not state this requirement. Another regulation ICH GCP includes that the Code of Federal Regulations does not, is the participant being informed of his expected responsibilities. ICH GCP specifies that trial procedures should be followed for all invasive procedures," whereas FDA refers to "experimental procedures". In regards to the "reasonable foreseeable risks", ICH GCP more specifically includes the embryo, fetus, or nursing infant, whereas the FDA refers to that possibility as "unforeseeable risks". ICH GCP is also more specific than the FDA by requiring the subject to be made aware that there may be no intended clinical benefit. It is also necessary under ICH GCP to inform subjects of the possible risks and benefits of alternative procedures or courses, and FDA does not.

The ICH GCP requires an explanation of the compensation in the event of a trial-related injury. However FDA specifically asks for this information in case of a research involving more than minimal risk and demands that the subject has to be informed what the injury treatments consist of and where further information can be obtained.
Another regulation ICH GCP contains that the FDA Regulations do not, is the notification of the "anticipated prorated payment, if any, to the subject for participating in the trial". Also, "the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the

applicable laws and regulations and that, by signing a written informed consent form," is a regulation of ICH GCP that is not required by the FDA. However, the FDA reserves the right to inspect the records without obtaining additional consent from the patient, but ICH GCP makes it clear that "if the results of the trial are published, the subject´s identity will remain confidential". ICH GCP includes a section with five points that is not in the FDA regulations regarding trials being conducted with the consent of a legally acceptable representative.

These five points are:
"1. The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally
2. The foreseeable risks to the subjects are low
3. The negative impact on the subject's well-being is minimized and low
4. The trial is not prohibited by law
5. The approval/favorable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/ favorable opinion covers this aspect".
The FDA also asks that the subject be informed of the consequences of withdrawing "from the research and procedures for orderly termination of participation by the subject," and that the subject is aware the clinical trial will be submitted to the clinical trial registry databank.

Global standard guideline

1) Basic elements:

(a) Statement that the trial involves research
(b) The purpose of the trial
(c) The trial treatment(s) and the probability for random assignment to each treatment
(d) A description of any trial procedures to be followed
(e) The subject's responsibilities
(f) Those aspects of the trial that are experimental
(g) Those procedures of the trial that are invasive
(h) The reasonably (un)foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant
(i) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this
(j) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks
(k) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so what they consist of, or where further information may be obtained
(l) The anticipated prorated payment, if any, to the subject for participating in the trial
(m) Any additional costs to the subject that may result from participation in the research

(n) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled

(o) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access

(p) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records

(q) If the results of the trial are published, the subject's identity will remain confidential

(r) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial

(s) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury

(t) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

(u) The expected duration of the subject's participation in the trial

(v) The approximate number of subjects involved in the trial

2) Additional elements:

(a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally

(b) The foreseeable risks to the subjects are low

(c) The negative impact on the subject's well-being is minimized and low

(d) The trial is not prohibited by law

(e) The approval/favorable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects and the written approval/ favorable opinion covers this aspect

(f) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject

(g) When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j) (1) (A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available onhttp://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Discussion

After a detailed comparison of the ICH GCP and CFR, the authors come to the conclusion that the ICH GCP contents contain much more detailed information and standards than the CFR. In particular, the ICH GCP contains nine points that are completely absent in CFR. On the other hand CFR includes only two elements that are not mentioned in ICH GCP. Furthermore, the two documents implicate six points that are listed in both but differ from each other in their detailed phrasing and meaning. Within these elements additional information can be found that is respectively missing in the other document.

To standardize and to simplify trial approvals on the world market, it is important to have a solid foundation to work with. Implementation of a standard guideline will improve the ethical and scientific quality of trials in the United States and the European Union.

Considering all the facts, the conclusion can be made that a combination of the ICH GCP and the Code of Federal Regulations would be a good solution for a study with an international background. In this case, no problems would occur when a study planned in a European country shall also be conducted in the United States because the informed consent form would be accepted in both countries.

Retrospectively, the authors evaluate the chosen methods as appropriate. The approach to contrast both documents in a table led to valid results.

List of abbreviations

ICH	International Conference on Harmonization
CFR	Code of Federal Regulations
FDA	Food and Drug Administration
GCP	Good Clinical Practice

References

1) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50
aufgerufen am 12.06.2012

2) http://ichgcp.net/48-informed-consent-of-trial-subjects
aufgerufen am 12.06.2012

Annex

ICH GCP	FDA – Code of Federal Regulations
(a) That the trial involves research	A statement that the study involves research (1)
(b) The purpose of the trial	an explanation of the purposes of the research (1)
(c) The trial treatment(s) and the probability for random assignment to each treatment.	
(d) The trial procedures to be followed, including all invasive procedures.	A description of the procedures to be followed (1)
(e) The subject's responsibilities	
(f) Those aspects of the trial that are experimental.	identification of any procedures which are experimental. (1)
(g) The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant	A description of any reasonably foreseeable risks or discomforts to the subject. (2)
(h) The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this	A description of any benefits to the subject or to others which may reasonably be expected from the research (3)
(i) The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. (4)

(j) The compensation and/or treatment available to the subject in the event of trial-related injury	For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so what they consist of, or where further information may be obtained (6)
(k) The anticipated prorated payment, if any, to the subject for participating in the trial	
(l) The anticipated expenses, if any, to the subject for participating in the trial	Any additional costs to the subject that may result from participation in the research (Additional 3)
(m) That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled	A statement that participation is voluntary, that refusal to participate will involve no penalty of loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. (8)
(n) That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority(ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access	

(o) That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records (5)
(p) That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial	A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject. (Additional 5)
(q) The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. (7)
(r) The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent. (Additional 2)
(s) The expected duration of the subject's participation in the trial	the expected duration of the subject s participation (1)
(t) The approximate number of subjects involved in the trial	The approximate number of subjects involved in the study. (Additional 6)
Non-therapeutic trials may be conducted in subjects with consent of a legally acceptable representative provided the following conditions are fulfilled:	
(a) The objectives of the trial cannot be met by means of a trial in subjects who can give informed consent personally	

(b) The foreseeable risks to the subjects are low	
(c) The negative impact on the subject's well-being is minimized and low	
(d) The trial is not prohibited by law	
(e) The approval/favourable opinion of the IRB/IEC is expressly sought on the inclusion of such subjects, and the written approval/ favourable opinion covers this aspect	
	A statement that the particular treatment or procedure may involve risks to the subject(or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable. (Additional 1)
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject (Additional 4)

	When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available onhttp://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why do volunteers participate in phase I clinical trials? An exploratory study

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Abstract

- Study goal: This study was carried out to answer the following research question: which motivation do healthy volunteers have to participate in phase I clinical trials?
- Methods: A literature search was done through Google Scholar and Academic Search Premier, followed by three interviews with volunteers who had recently concluded their participation in a (non-commercial) phase I trial.
- Results: Our literature search revealed mainly commercial motives for volunteers to participate in phase I clinical trials. The interviews (with volunteers in a non-commercial trial) showed that other factors may also play a decisive role, such as: (1) wish to support the investigator (2) wish to contribute to science, (3) access to more/better health care (4) sociability: possibility to relax and to communicate with other participants (5) general curiosity. Precondition is that risks and burden are deemed acceptable.
- Conclusions: financial remuneration appears to be the predominant motive to participate voluntarily in a clinical trial. Other reasons were also mentioned however, such as general curiosity, the drive to contribute to science and the willingness to help the investigator. In addition, social reasons were given such as possibility to relax and to meet other people. Potential subjects state that they adequately assess the (safety) risks of participating in a trial as part of their decision process.

Keywords

Phase I clinical trials; volunteer motivations to participate.

Introduction

The WAIT time [Waiting to Access for Innovative Therapies] is an important performance indicator in drug development. It is a major determinant for the speed with which new innovative drugs come to market and to the benefit of patients. It is defined as the time lapse that sponsors need to wait for third party decisions, e.g. to give their consent for clinical trials, market authorization and reimbursement, or to include the needed number of patients in the trials they sponsor (Van Dooren, 2012).

In the latter case it is important to know which motives healthy volunteers have to participate in phase I trials, so that sponsor companies may be able to anticipate these motives and inclusion speed may be increased. Hence, the research question for this study was as follows: *which motives do health volunteers have to participate in phase I clinical trials?* In phase I studies, safety aspects of new drugs are tested in humans for the first time. In healthy volunteers the new drug is

administered in increasing doses and safety effects (adverse events) are recorded. Metabolic processes such as resorption and elimination may also be studied (Bortel, 2011).

Methods

A literature search in Google Scholar and Academic Search Premier was carried out using the following (combinations of) search terms: inclusion clinical (drug) trials, (rules / regulations) participation in (clinical) (drug) trials, participation in phase I trials (studies), healthy volunteers, clinical research.

Subsequently, three persons who had participated in a non-commercial clinical trial – aiming to study how enzymes metabolize a standard antitussive drug formulation - were interviewed to learn more about their motives to participate.

Results

There is a dearth of papers in scientific journals dealing with volunteer motives to participate in phase I studies. Stunkel and Grady (2010) found in their literature study that financial compensation is the main motive for individuals to participate, but additional reasons are the wish to contribute to science, interest in the study, possibility to meet other individuals or just curiosity. Rabin and Tabak (2006) argued that ideally individuals should base their decision whether or not to participate on perusing and understanding the information given in the Informed Consent (IC). However, they found that only 35% do so. The ethical implications of remuneration of included volunteers are described in a recent BMJ paper (Liddell, 2010). Liddell stated that individuals are free to do with their bodies what they want, so it is logical they get paid for the risk they have. His opponent, J. Saunders, countered that persons should not be exposed to health hazards because of receiving a remuneration. '*A risk may be low when the hazard is high'.*

Almeida et al (2008) divided volunteers in two groups bases on their scores on (social) anxiety and depressive symptoms and then checked their willingness to participate in phase I trials. They found that these participants can be defined in terms of low trait-anxiety and social avoidance behaviours. This self-selection bias may affect study results because less anxious individuals tend to report fewer adverse events.

A very recent study by Nappo et al (2013) also found that the most frequently encountered motivations were financial gain and therapeutic alternative. Altruism was not a common motivator and when it was present it was only secondary.

Motivations for volunteering for clinical trials as derived from literature can be summarized as follows in Figure 1.

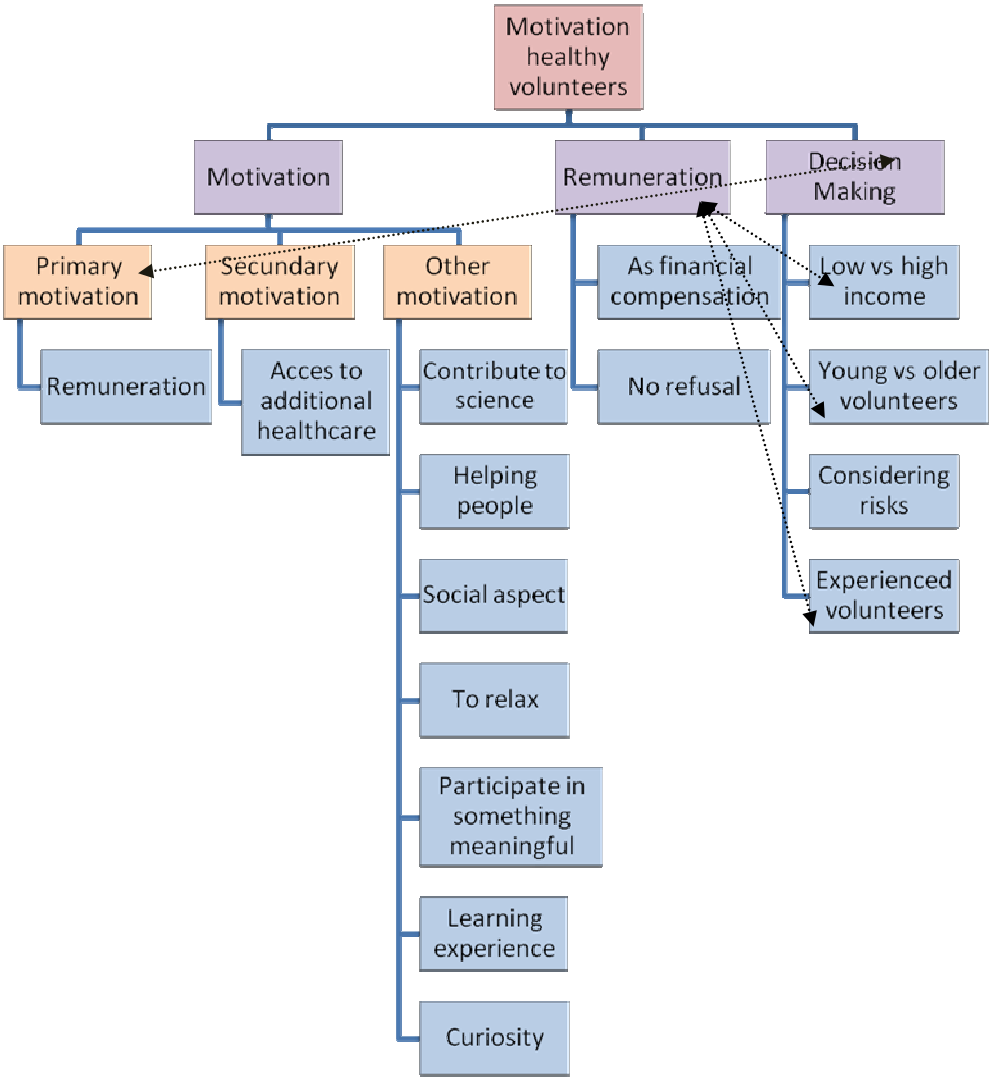

Figure 1. Motivations for volunteering for clinical trials

If remuneration is involved, this is usually the primary reason to participate. Low income individuals more frequently choose remuneration as primary motive, as compared to high income individuals. The same applies to younger volunteers, who more often mention payment as the primary reason, in comparison with older persons. Also, people having more experience in clinical trial participation mention remuneration as their prime reason.

Subsequently we carried out semi-structured interviews with three volunteers in a non-commercial trial. All three had a job in health care. The motives they mentioned are summarized as follows in figure 2.

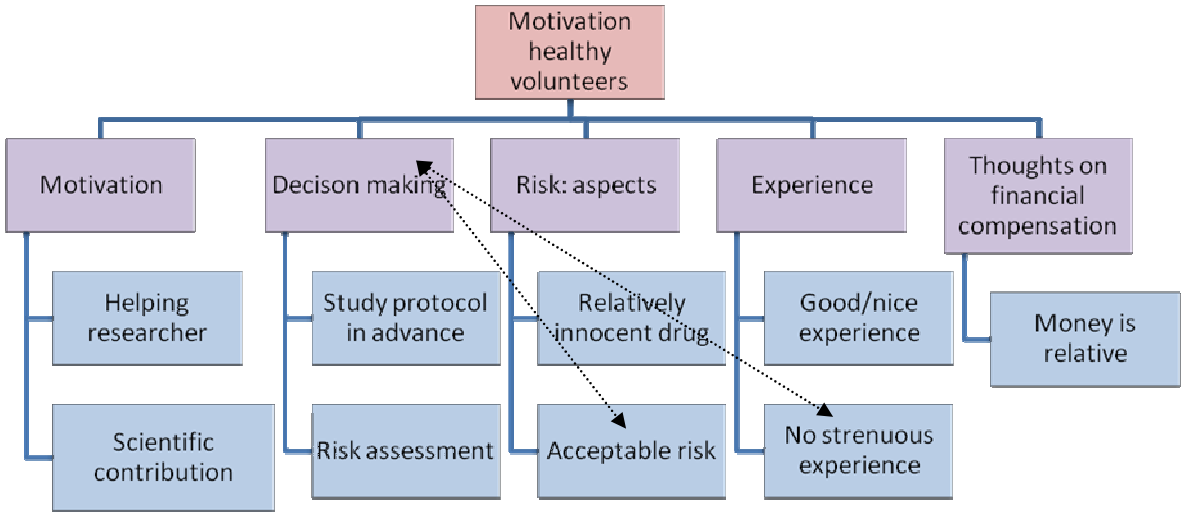

Figure 2. Motivations for volunteering in non commercial clinical trials

The main reasons as mentioned by the respondents were the wish to help the investigator and to make a contribution to science. Before a decision was made the protocol was first perused and risks were assessed. All three respondents had participated in a trial with an antitussive which they regarded relatively safe, so they thought the risks were acceptable. They had not received a financial compensation but after the trial they got a gift certificate, worth €25. They thought this was a nice side issue but having no influence on the decision to participate. Before deciding to join they first assessed the risk and how cumbersome the trial activities seemed to be. Because in this particular case the trial was no burden they mentioned they would certainly be willing to participate a next time again.

Discussion

This is a small research study, carried out by a student as her bachelor's thesis. It consists of a literature search plus three non-random interviews with respondents who had volunteered in one and the same investigator-initiated (non-commercial) phase I safety study. Despite the fact that the results may not be generalized, there seems to be sufficient evidence for concluding that financial motives play a predominant role in the decision whether or not to participate as a volunteer in a phase I clinical trial. But in addition, other motives such as general curiosity, the drive to contribute to science and the willingness to help the investigator have been mentioned. The latter reason is doubtful from an ethical point of view; in The Netherlands it is preferred practice to have a physician other than the investigator to explain the study and IC (Informed Consent) to possible subjects, in order to avoid even the slightest appearance of coercion. Whether or not financial remuneration for volunteering subjects is ethical, is also a matter of

debate (Liddell, 2010). That things can go enormously wrong has been shown abundantly in the past: the Tegenero/ Parexel disaster is a well-known example (Suntharalingam et al, 2006). Our respondents state they judge the possible risks adequately, but particularly in case of a new drug product not tested before in humans, there is always a level of uncertainty.

The finding that subjects also mention 'possibility to relax' and 'possibility to meet other people' as motives to participate, was not expected by us. It remains to be seen whether this is something special for participants in this particular trial or whether it would be found in other studies too.

Recommendations

It is recommended that this initial study be followed by larger studies to include:

- Larger numbers of respondents in order to be able to draw statistically significant conclusions
- Respondents from various countries and cultures
- Respondents from various types of phase I studies (sponsor company/investigator initiated trials, drug/non-drug trials etc)
- Respondents of different social classes, gender, profession, age etc.
- Likert scales on remuneration levels and risk levels to get an insight in the link between payment and risk assessment

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Abstracts of posters from

1st Indo-European Pharmaceutical Drug Development Conference

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001

Advances in Management Of Gastric Cancer

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ABSTRACT

Gastric cancer represents a challenging health problem around the world and is one of the top causes of cancer-related deaths. Challenges in treatment of advanced gastric cancer are due to the relative resistance of disease to treatment, the frequent occurrence of symptomatic disease or impaired performance status of patients, and the propensity of gastric cancer to present when it has become locally advanced or metastatic. Recently, remarkable progress in tumor biology has led to the development of new agents that target critical aspects of oncogenic pathways. This presentation provides an updated summary of the current status of gastric cancer diagnosis, management, cytotoxic chemotherapy, emphasize on many chemotherapeutic options available and the reasoning that clinicians use in choosing the right treatment option for the right patient.

As per the current clinical trial studies the combination therapy shows promising success rate, Pac-5-FU(56%), Cape-Cis(55%), DCF(54%), UFT-Cis(51%), CPT-Cis(50%), 5-FU-Oxal(48%), FOLFOX-4(45%). The advances in individualization of therapy offer a treatment care plan with a high rate of success and minimal toxicity. Recent progress in treatment of gastric cancer includes Biologically targeted therapies (a recombinant humanized monoclonal antibody to vascular endothelial growth factor), Monoclonal Antibodies and tyrosine kinase Inhibitors, pharmacogenomics, predictive markers of response, surrogate markers of response whose scope will only increase as the understanding of the pathophysiology and carcinogenesis of this disease improves.

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Clinical trials on Cancer: A boon for eradication of cancer from India

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ABSTRACT

Introduction: Cancer clinical trials test many types of treatment such as new drugs, new approaches to surgery or radiation therapy, new combinations of treatments, or new methods. Cancer clinical trials are the first step in testing a new treatment in humans and their goal is to find better ways to treat cancer.

Prevalence of cancer in India and need of cancer trials: Over 5.56 lakh deaths in India were reported due to cancer in the year 2010. According to a global survey India had 845,200 (5-10%mortality) deaths due to cancer in the year 2002, it is estimated that the number would rise to

1,389,800 (25-50% mortality) till 2020. Thus despite of recent advances in cancer care, there is a still a significant need for more treatment options.
To address this need, many private and public institutions focus their research on understanding different cancer types and developing potential medicines. Each new medicine in development in the India must go through a comprehensive clinical trial process that is registered with the Food and Drug Administration (FDA) to ensure that products approved for patient use are safe and effective.

Cancer trial benefits and risks: Participants have access to promising new treatment methods that are often not available outside the clinical trial setting. Participants may be the first to benefit from the new method under study. But at the same time new drugs or procedures under study are not always better than the standard care to which they are being compared. New treatments may have side effects or risks that doctors do not expect or that are worse than standard care.

Statistics of cancer trials in India: From the total number of clinical trials, the largest proportion of the drug trials is for cancer drugs, 13.4% of all trials i.e. over 18000 clinical trials on cancer are carried in India till date.

Conclusion: Thus despite of recent advances in cancer care, there is a still a significant need for more treatment options.

003

Nigella Sativa for Cancer treatment

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ABSTRACT

It is ironic but true that the treatment of diseases started from herbs then shifted to chemical allopathic drugs and now we are once again reverting to herbs thanks to the side-effects produced by allopathic medicines.

Nigella Sativa (Family: Ranunculaceae) is an annual flowering plant, also known as Kalijiri in Hindi. It has a pungent bitter taste and faint smell of strawberries. It is mainly used as a spice and also in the preparation of candy and liquor.

Nigella Sativa has a potential anti-inflammatory, anti-microbial, anti-fungal, anti-parasitic, and anti-cancer activity. The anticancer activity is proven for myeloid lymphoma and leukemia. N. Sativa alone or in combination with oxidative stress were found to be effective in vitro in inactivating MCF-7 breast cancer cells, unveiling opportunities for promising results in the field of prevention and treatment of cancer. The seeds of Nigella sativa contain proteins and other compounds called saponins and alkaloids. They also contain several oils and a natural chemical thymoquinone. Thymoquinone has significant anticancer activity. It is widely distributed is cheaply availaible. The mechanism of action is unknown.

004

Microwave Imaging Technology for Breast Cancer

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ABSTRACT

Conventional mammographic detection techniques have many drawbacks and often cause harm to patients. The invention of non-invasive and non ionizing microwave technique to reveal the internal structure of biological objects thus became a breakthrough in the field of medical diagnostics. When exposed to microwaves, breast tumor exhibits electrical properties that are significantly different from that of healthy breast tissue and hence detection of the tumor in terms of dielectric contrast is possible. The variation of dielectric properties of tissues upon exposure to microwaves is the underlying principle of microwave imaging. Microwave technology makes important contributions to both therapeutic and diagnostic medicine. The depth to which microwaves can penetrate tissues is primarily a function of the dielectric property of the tissues and of the frequency of the microwaves. When microwaves penetrate into the tissues, they give up energy to the tissues thus non-invasively producing hyperthermia, particularly in cutaneous and subcutaneous cancer sites thus inducing even death of cancer cells. This most promising therapeutic medical application of microwave seems to have no side effects and continues to be effective as the body does not get accustomed to it. The results are remarkable when microwave technology is combined with radiotherapy and chemotherapy. It is reported that high power microwave pulses can enhance the ability of certain chemotherapeutic agents to enter malignant cells. The rationale for pursuing electromagnetic methods are - I) significant difference in the electrical properties of normal and malignant breast tissues in the microwave spectrum, 2) microwave illumination can effectively penetrate the breast, 3) As breast is a small readily accessible tissue volume, it is an ideal site for deploying advanced near field imaging concepts that exploit model based image reconstruction methodology.

The unique features of microwave breast imaging are that it

- offers low health risk
- sensitive to tumors and specific to malignancies
- detects breast cancer at a curable stage
- non-invasive and simple to perform
- cost effective and widely available
- involves minimal discomfort
- provides easy to interpret and consistent results.
- no side effects
- minimum discomfort to the patient

005

Molecular Mechanism Involved In Apoptosis of Colon Cancer through Orexin Receptor.

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ABSTRACT

Colon cancer is a leading cause of cancer mortality in many countries. Molecular genetic studies have identified key genes whose mutations or altered expression can cause colon cancer. Many observations also indicated that colon cancer growth is under the control of a variety of peptide growth factors acting at tyrosine kinase receptors or G protein-coupled receptors. Resistance to apoptosis is a recurrent theme in colon cancer. An exciting aspect of the heptahelical orexin receptor 1 (OX1R) has emerged recently, when it was shown that it drives apoptosis in human colon cancer cell lines. Here we review recent findings related to the role of OX1R in colorectal cancers and the unexpected mechanism whereby this G protein-coupled receptor works. Treatment of human colon cancer cells in culture with orexins promotes robust apoptosis and subsequent reduction of growth including in cells that are resistant to 5-fluorouracil, the most commonly used drug in chemotherapy. OX1R triggers apoptosis by an entirely novel mechanisms which is not related to Gq-mediated phospholipase C activation and cellular calcium transients. Orexins induce tyrosine phosphorylation of two immunoreceptor tyrosine-based inhibitory motifs (ITIM) in OX(1)R and subsequent recruitment by OX(1)R of the phosphotyrosine phosphatase SHP-2, which is activated thereby. The activation of which is responsible for mitochondrial apoptosis. Thus, OX1R agonists might be novel candidates for colon cancer therapy. The role of ITIMs in OX1R-driven apoptosis represents a new paradigm of G protein-coupled receptor signaling.

006

Stem Cell Therapy: Potential Treatment for Cancer Cure

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ABSTRACT

Conventional chemotherapy treatments along with killing of tumour cells, kills chunk of healthy cells leading to myelosuppression and still occurrence of relapse. Where the conventional therapies fail, “STEM CELL THERAPY” may not only serve as a vehicle in targeted delivery of chemotherapeutic agents but also by inducing genetic changes may kill the tumour cells especially the cancer stem cells which have tumour initiating potential and are responsible for the growth of the tumour. Normal stem cells may get mutated to form cancer stem cells leading to tumour. During chemotherapy, most of the primary tumour cells may be destroyed but if cancer stem cells are not eradicated, they lead to recurrence of tumour and thereby metastasis. So the problem lies in identification of cells capable of sustaining neoplastic growth.

1. One approach to target the cancer stem cells may be the identification of the markers that are specific for the cancer stem cells compared to normal stem cells.

2. Stem cells act as delivery vehicles as they send out chemo-attractants viz. the vascular endothelial growth factor (VEGF) to recruit stem cells to form the supporting stroma of the tumour, and pericytes for angiogenesis.

3. Stem cells along with the pro drug when transplanted migrates into the cancerous area and expresses cytosine deaminase that converts a non-toxic pro-drug into a chemotheraputic agent killing the surrounding tumour.

4. Stem cells may be induced with the chemotherapeutic gene of the natural agents like vinca alkaloids and then transplanted in the tumour which reported not only kills the tumour cells but also avoid its relapse.

It is concluded that apart from their use in the immuno-reconstitution, the stem cells have been reported to contribute in the tissue regeneration and as delivery vehicles in the cancer treatments and has the potential to destroy residual tumor cells. It also improved patients' quality of life by minimizing toxic side effects such as nausea, diarrhea or bone marrow suppression, localized therapeutic effect, no damage in any other cells.

007

Clinical Trials: A Guide for Innovative Cancer Therapy

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ABSTRACT

In the field of management of cancer, scientist and doctors are constantly looking to develop innovative, more effective and less toxic treatments for the improvements in patient's survival and quality of life. Cancer clinical trials are studies conducted with patients and are generally designed to confirm the safety and effectiveness of a new promising treatment. Before any new treatment is made available for testing in patients, it must be thoroughly tested in a laboratory on cell cultures and on animals. Only when these preclinical (and animal) studies suggest that the treatment is safe, it is then tested in clinical trials with patients. In cancer research, some clinical trials are aimed at discovering new drugs while others evaluate and optimize different therapeutic approaches including surgery, radiation therapy and combinations of drugs already on the market. The purpose of the trial may be to test different doses of the treatment, how often it should be taken, and whether it is best to take it for example as tablet or injection. To address this need many private and public institutions focus their research on understanding different cancer types and developing potential medicines. Clinical trials are carefully controlled research studies in which people volunteer to participate. Thus, clinical trials severs a excellent platform for the screening of effective and novel drugs of natural and synthetic origin to fight against cancer in a systematic and target oriented drug treatment.

008

Colorectal Cancer: Basic understandings to Advance approaches

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Abstract

Colorectal cancer (CRC) is the third most common cancer worldwide, highest in North America and western countries. It is a prevalent disease that is associated with considerable mortality and morbidity rates, with more than 1,000,000 new cases and 500,000 deaths annually. This disease is preventable in more than 90 % cases by some of the basic modifications in lifestyle, like balanced diet, avoidance of smoking and alcohol and moderate physical activity etc. The non-compliance of traditional diagnostic method leads to large part of the average population not undergoing a screening process. The recent advancements in diagnostic methods i.e., virtual colonoscopy and stool genetic testing as well as chemoprevention methods has reduced the mortality rate from CRC. Our presentation includes, systemic approach of single or combinatorial chemotherapy, adjuvant and neoadjuvant treatment, surgical approach and advanced approaches of use of targeted biological agents in combination. Mentioning here one of the examples is the antitumoral effect exerted by antiangiogenic anti-VEGF agents such as bevacizumab/Avastin in expending up to 6 months the life span of CRC patients who are concomitantly treated with standard therapy such as FOLFOX (5-Fluorouracil, Folinic acid and Oxaliplatin)

At the end, the role of the pharmacist cannot be neglected in creating awareness and educating the community for preventive measures to be taken for colorectal cancer. The compliance of chemotherapy can be improved if patients are made aware of adverse effects and how to manage them and here comes the vital role of the pharmacist.

009

NLRP12 Protein Protects Against Colon Cancer

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ABSTRACT

It has been seen that in pre-clinical models, the absence of a protein called NLRP12 significantly increases susceptibility to colitis-associated colon cancer. Colorectal cancer, commonly known as colon cancer or bowel cancer, is a cancer from uncontrolled cell growth in the colon or rectum (parts of the large intestine), or in the appendix. Symptoms typically include rectal bleeding and anemia which are sometimes associated with weight loss and changes in bowel habits. Most colorectal cancer occurs due to lifestyle and increasing age with only a minority of cases associated with underlying genetic disorders. It typically starts in the lining of the bowel and if left untreated, can grow into the muscle layers underneath, and then through the bowel wall.

The NLR family of proteins is very complex and scientists have determined that the majority of them act as activators of inflammation. However specifically NLRP12 protein actually functions to reduce disease by inhibiting a major inflammatory pathway mediated by a protein called NF-Kappa B.

This finding would greatly help in protection against colon cancer. A person suffering from colon cancer and be treated by administration of such protein. But further studies are needed to be done in order to better understand the NLR family of proteins.

010

Newer techniques for detection of lung cancer

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ABSTRACT

According to current global updates and today's current scenario it has been estimated that about 30 % morbidity rate is due to cancer. Cancer being a fatal & non-symptomatic disease needs fool proof and precise technique for its early detection. Out of all types of cancer lung cancer is the most prominent cancer throughout the globe which is generally caused due to smoking addiction and various other reasons. Each year, more people die of lung cancer than of breast, colon, and prostate cancers combined. There are many conventional techniques available still been used today for detection of lung cancer which includes X-ray, C.T scan, (PET) positron emission tomography, bronchoscopy, blood tests etc. The newer detection techniques which are more precise and accurate helps to detect cancer at an early stage and also used to uncover some advance cancers. The newer detection techniques which includes auto fluorescence bronchoscopy, navigational bronchoscopy, endobronchial ultra sound, digital chest tomo synthesis, endoscopy and many more techniques are been proving to be helpful for early lung cancer detection. It has been estimated by experts that by 2030 the rate of cancer would be twice as compared to today's scenario and hence being an alarming condition, global awareness, precautions and all possible steps should taken to overcome and fight against this deadly disease & for this newer techniques should be utmost precise and accurate for early detection.

011

Skin cancer management and role of pharmacist

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ABSTRACT

Pharmacist is a link between the doctor and patient. Pharmacist playing a vital role in health care system especially, in terms of creating awareness among the society on prevention of certain diseases and role of hygiene in it. There are number of diseases like, colon cancer, skin cancer and

likewise can be prevented up to certain extent by adopting changes in life style. Our humble attempt in this presentation is to summarize some basics information and treatment available on skin cancer and its management. Pharmacist with detailed knowledge of pharmaceutical dosage forms and therapeutic agents with their desired effects, potential hazards, and adverse effects of the drugs can play vital role in community healthcare system.

Chemotherapy, radiation and surgery are accompanied with several harsh side effects. The non-compliance to treatment and its regimen is mainly due to its undesirable side effects. For example, you may have minor skin problems while you are having chemotherapy such as redness, rashes, itching, peeling, dryness, acne, and increased sensitivity to the sun. Certain anticancer drugs, when given intravenously, may cause the skin all along the vein to darken, especially in people who have very dark skin. Some people use makeup to cover the area, but this can take a lot of time if several veins are affected. The darkened areas will fade a few months after treatment ends.

012

FDA-approved Drug Makes Established Cancer Vaccine Work Better

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Cancer, known medically as a malignant neoplasm, is a broad group of various diseases involving unregulated cell growth. It is usually treated with chemotherapy, radiation therapy and surgery. The chances of surviving the disease vary greatly by the type and location of the cancer and the extent of disease at the start of treatment. The term cancer vaccine refers to a vaccine that prevents infections with cancer-causing viruses, treats existing cancer or prevents the development of cancer in certain high risk individuals. Scientists have also been trying to develop vaccines against existing cancers. Most cancer vaccines work like other vaccines, but they usually prime the immune system to attack cancer cells in the body.

A research study has shown that daclizumab, already used for kidney transplantation, would be effective in depleting regulatory T cells (Tregs) and restoring the immune system's ability to fight tumors. Tregs are an important population of white blood cells that help turn off the immune system when the system's job is done. Tregs can block the immune response against most human cancers. Tregs rely on a particular protein, called IL-2, for most of their functions. Tregs are deprived of IL-2 in the presence of daclizumab. Thus it was found that drugs like daclizumab might be useful for most cancer patients, especially to those receiving other types of immune therapy.

Although there is a great deal of work to do to confirm the findings researchers believe this will have major implications for cancer vaccine regimens in other types of cancer.

013

PHASE 0 TRIALS: A BOOST FOR SUCCESS OF CLINICAL TRIALS

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ABSTRACT

Anti-cancer drug discovery begins in the laboratory with target identification and validation followed by pre-clinical and clinical development. The entire process takes around 10 to 15 years. It is associated with high costs and a high rate of failure. Phase 0 clinical trials provide a unique opportunity to gather preliminary evidence on the effects of drugs without exposing patients to potentially toxic doses. At the same time decisions could be made regarding further development of drugs very early in clinical development and ineffective drugs could be eliminated, thereby reducing development costs. Phase 0 is a recent designation for exploratory, first-in-human trials conducted in accordance with the United State Food and Drug Administration 2006 "Guidance on Exploratory Investigational New Drug Studies". The objective of introducing Phase 0 trials is to create opportunities for innovations in the drug development network and to make the process more efficient, effective, and safe that will benefit patients. Phase 0 trials entail administration of single sub therapeutic doses of study drug to a small number of subjects (10 - 15) to gather preliminary data on the agent's pharmacokinetics and pharmacodynamics. Drug development companies carry out phase 0 studies to rank drug candidates to identify the drug having superior pharmacokinetic and pharmacodynamic parameters in humans to take forward into further development. Phase 0 clinical trials can provide a platform to assess the biological effects on the target in human tumor samples, evaluate biomarkers for drug effects before initiating larger trials involving patients receiving toxic dose of study agent. It is expected that such trials will became a routine part of early-phase oncological drug development in the future.

014

Paediatric cancer – from psychological and social viewpoints

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ABSTRACT

Paediatric cancer is a speciality discipline in medicine concerned with diagnosing and treating children upto the age of 18 with cancer of any kind. It has been noted that children respond better to various anti-cancer treatment but a high mortality rate has still been observed.

The most common forms of paediatric cancer are leukemia, lymphoma, brain cancer and in later teen years, osteosarcoma (bone cancer). Globally, in every million people suffering from cancer, 147 are below the age of 18. 1.6 to 4.8% of all cancer in India is seen in children below 15 years of age and the overall incidence of 38 to 124 per million children, per year.

For the child affected with cancer, dealing with the condition is nothing less than traumatic, may it be bearing physical pain and side effects of the treatment they are undergoing, or the social issues they must face. For example, children are not aware of the fact that cancer is not contagious, ergo many a times the cancer affected child is isolated amongst his/her peers which puts emotional strain on him/her. This leads us to a significant aspect of childhood cancer – the psychological aspect. Pharmacists can also, along with providing anti-cancer medicines and drugs;

1. Provide psychological assistance to the child
2. Help spread awareness amongst children to rid society against the social stigma about cancer.

We, as pharmacists can take out time to talk to affected children about their condition, etc, in this way providing the much needed emotional support for them. This may be through official counselling sessions or otherwise. We can afford to do this as only a small number of children are inflicted with cancer. We can make a difference in the lives of these young ones.

015

Nanoparticle: a novel tool for cancer detection

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ABSTRACT

It is novel method, in which, total serum proteins are isolated from blood plasma by membrane electrophoresis and mixed with silver nanoparticles to perform SERS spectral analysis. The obtained SERS spectra show information-rich, fingerprint-type signatures of the biochemical constituents of whole proteins. The result obtained by analysing blood plasma samples from patients with gastric cancer and healthy volunteers. Principal components analysis of the spectra revealed that the data points for the two groups form distinct, completely separated clusters with no overlap. The gastric cancer group can be distinguished from the normal group in this initial test—that is, with both diagnostic sensitivity and specificity of 100%. These results are very promising for developing a label-free, non-invasive clinical tool for cancer detection and screening.

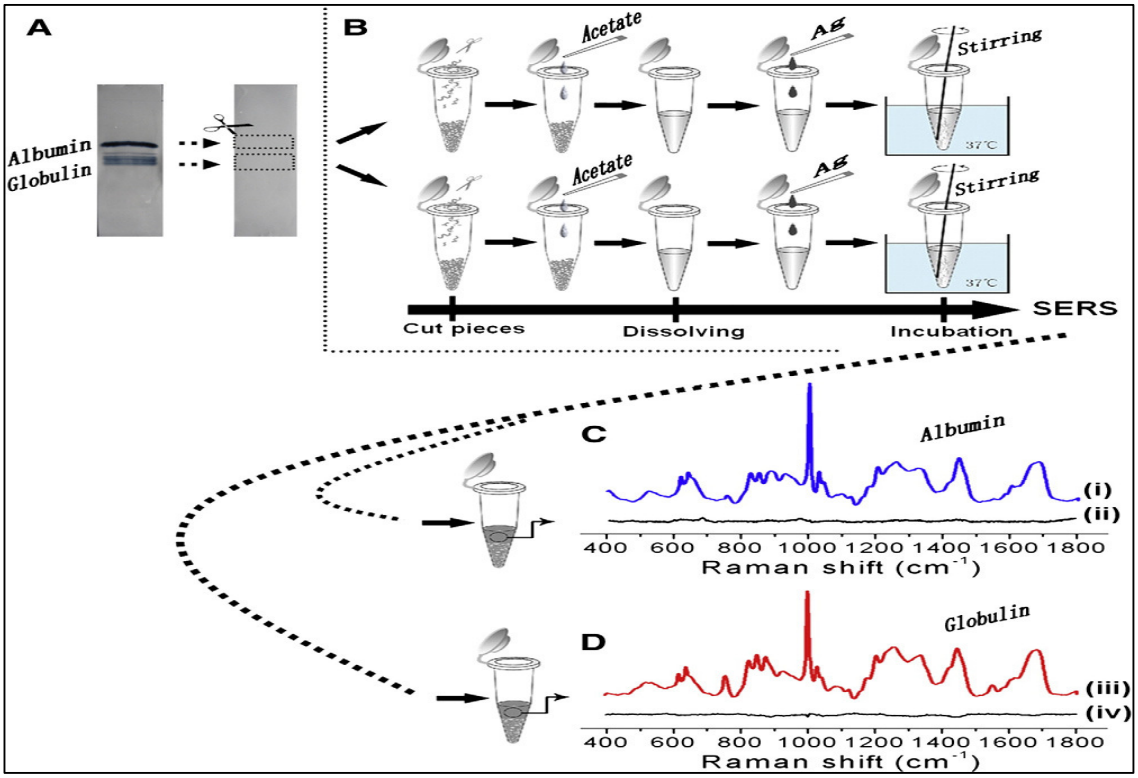

Figure 1: Schematic of the procedure for preparation of blood plasma protein-Ag NP mixtures.

Gold nanospheres are linked by a Raman active dithiolated linker molecule forming dimer and trimer assemblies. Gold Nanoparticle Dimers can also be used for SERS-Based Targeted Detection of Human Glioblastoma Cells. Assembling metal nanoparticles into organized nanostructures are paramount for the fabrication of reproducible, stable, and highly active SERS substrates.

016

Cancer clinical trials: an Indian perspective

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ABSTRCT

Cancer is the uncontrolled growth of abnormal cells in the body. Cancer grows out of normal cells in the body. Normal cells multiply when the body needs them, and die when the body doesn't need them. Cancer appears to occur when the growth of cells in the body is out of control and cells divide too quickly. It can also occur when cells forget how to die. Cancer clinical trials are research studies that involve people with cancer. The goal of these studies is to find better ways to diagnose, treat, and prevent cancer so that people can enjoy better and longer life. The studies also give us more information about reducing cancer risk in healthy individuals. Before a new

preventive or therapeutic approach is made available to the public, it must undergo a series of clinical trials.

Cancer Clinical trials in India are conducted in medical practices nationwide by cooperative research groups, the pharmaceutical industry, cancer centres and other academic and hospital centres. They test a treatment's safety and effectiveness for a particular type of cancer. Three phases of a clinical trial must be successfully completed before the FDA grants approval for marketing. Phase I establishes dosage and measures toxicity; Phase II evaluates whether there is a positive effect against the cancer; and Phase III compares the new treatment with the current standard of care. Cancer clinical trials offer hope for many. In clinical trials, cancer patients receive either the current best-known treatment or the opportunity for a new one. Unlike in other drug trials, in cancer treatment trials, placebos are rarely used, and they are never used in place of the best existing treatment for a given cancer. In India understanding attitudes toward cancer clinical trials is crucial for removing obstacles that hinder higher participation rates. Last year, TATA MEMORIAL HOSPITAL conducted a survey of public attitudes toward cancer clinical trials. The study revealed that the public has a number of misconceptions about clinical trials. They include the fear of receiving a placebo, concern over being treated like a "guinea pig" and fear that insurance will not cover costs. In order to fight this dreadful enemy (cancer) more contribution is expected from every corner of every Indian society.

017

Quantum dot: magic nanoparticle for imaging, detection and targeting of cancer

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ABSTRACT

Cancer is the leading cause of death worldwide, which is associated with an uncontrolled growth of cells. Cancer must be detected and controlled in early stages in order to cure the patient. One of the latest method for cancer detection is a Quantum dots (QDs), which are semiconductor nanocrystals that emit fluorescence on excitation with light source. As compared to organic dyes and fluorescent proteins QDs have unique optical properties such as a tunable emission spectra, improved brightness, superior photostability and simultaneous excitation of multiple fluorescence colour. Generally QDs made from Group II and Group IV elements (e.g. Cd, Se and Cd, Te) or Group III and Group VI element (e.g. In, P and In, As).

These nanocrystals (i.e. QDs) could enable to detect many cancer biomarkers in blood assay, on cancer tissue biopsies or as contrast agent for medical imaging. Conjugation of QDs with biomolecule, including peptide and antibodies, could be used to target *in vivo.* Combination of different size QDs within a single bed can create probes that release distinct colour and intensities of light. Multicolour QDs staining method provides rapid detection and identification of rare malignant cells from heterogeneous tissue specimen. Advantages of this technique are ease of preparation, fast detection and highly sensitive. These QDs have diagnostic application in various cancers such as pancreatic, breast and hepatic cancer etc.

018

Detection of carcinoma cells using cell microarray chip

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ABSTRACT

Circulating Tumour Cells (CTCs) in the bloodstream play an important role in the metastatic spread of cancer. CTCs are extremely rare in healthy subjects and patients with non-malignant tumours. However, they are present at a higher frequency in the bloodstream of patients with metastatic carcinomas. Diagnosis of specific CTCs at an early stage can help in devising personalized anticancer therapy and prevent metastasis of the tumour. Cell-based microarray chips can be constructed for their detection. Cell-based microarrays are a variation on the standard microarray format, which allow living cells to adhere to the surface of the chip microchambers. Cell microarray chips with microchambers can be used to allow high throughput and highly sensitive analysis of CTCs. Enrichment of blood sample, obtained from the patient, with CTCs can be done by using the monoclonal antibody anti-EpCAM (Epithelial Cell Adhesion Molecule CD326) and anti-CD45 to discriminate the leukocytes. The enriched carcinoma cells and human leukocytes can then be dispersed onto the cell microarray chip and allowed to settle into the microchambers. Upon washing off the nonadhered cells, carcinoma cells can be stained using fluorescently labelled anti-cytokeratin monoclonal antibodies which are specific for cytokeratins 7 and 8 and will help in distinguishing between epithelial cells and the contaminating leukocytes. Fluorescencepositive CTCs can be detected using a microarray scanner with a confocal fluorescence laser. Hence by using cell microarray chips, CTCs can be accurately detected by determining the protein expression on the membrane of cancerous cells using monoclonal antibodies, thereby helping further in the specific therapy.

019

Newer technique in cancer detection

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ABSTRACT

Modern imaging techniques such as computed tomography (CT) and ultrasound (US) are in the majority of cases able to detect local and metastatic spread of malignancy. Increasingly, the requirement is for even more accurate preoperative tumour staging to enable the use of new surgical techniques, neoadjuvanttherapies and, postoperatively, to enable detection of tumour recurrence on follow-up. The information obtained from this technique is useful in distinguishing between recurrent/residual tumor and post-treatment changes and assessing treatment response, with a clear impact on patient management. This technique provide innovative tools that shed greater light on life cycle of normal cells and the point at which molecular processes and changes within cells become correlated with development of cancer. It should be possible to obtain large

amount of information from a small source. They aid in analysis of parameters such as cellular mechanics, morphology and cytoskeleton which has been hard to achieve using conventional technology. This technique can detect cancer cells, identify cancer signatures and provide targeted delivery of anti-cancer therapeutics and contrast agents to tumour cells. The obstacle to early detection of cancer lesion the liability of existing tools to detect molecular level changes during early phases in the development of cancer. This technique is potential tool that could help detect the molecular changes and assist in focusing on preventive efforts.

020

Monoclonal antibody for metastatic breast cancer

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ABSTRACT

Causing about 13.7% of death in woman worldwide in a year, breast cancer becomes one of the important cancers whose treatment needs to be optimized. To add on to the complication in the treatment, comes forth the metastatic breast cancer that spreads to distant metastasis. HER2 or Human Epidermal Growth Factor Receptor 2 found on the surface of the breast cancer cells binds to the hormones causing changes in the cells. Amplification of HER2 results in development of the pathogenesis of various types of breast cancer, which in itself becomes the target for treating the cancer.

Therapies used to treat metastatic breast cancer ranges from the conventional Chemotherapy to Radiotherapy and Nanotherapy but something to stand out amongst these in terms of efficiency is the Monoclonal Antibody. Monoclonal antibodies produce antibodies of a single type, which are much more specific in action as compared to the polyclonal antibody. Monoclonal antibodies act specifically against cancer antigen thus preventing the spread of the tumor. Keeping in mind the theme of the event of drug development, we are going to talk about the scope in development of monoclonal antibodies in cancer treatment.

The present poster discuses the US FDA approved drugs based on the concept of monoclonal antibody, for metastatic breast cancer. A review will also be made on the clinical trials of these drugs so as to find further scope of corrections and improvement in the treatment.

021

Design, synthesis and evaluation of novel RTK-inhibitors as potential anticancer and anti-proliferative agents

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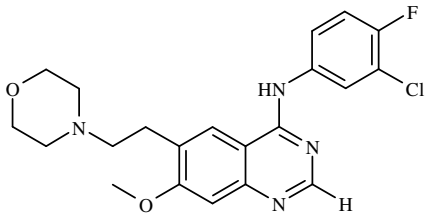
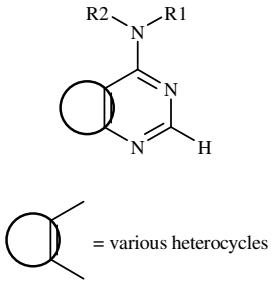
A series of novel condensed 2-*H*-pyrimidin-4-amines, as bioisosteric analogs of well known antiproliferative anticancer drug, Gefitinib, has been designed and synthesized by a one-pot MWI based synthetic protocol. The newly synthesized compounds have been evaluated for antiproliferative & antitumour activities by *in-vitro* testing against 5 different cancer cell lines [EAC (Ehrlich Ascites Carcinoma), A549 (Lung Carcinoma), HT-29 (Adenocarcinoma), MDA-MB 231(Breast cancer) & HeLa (Cervix cancer) cell lines] and many of the compounds have revealed excellent potential to be developed as anticancer drugs as the PIC_{50} values of some compounds are better than that obtained for Gefitinib.

The 3D-QSAR work for the optimization of 3D structural features, include studies by COMFA, CONISIA and PHASE. Further, docking studies with GLIDE reveal good binding with RTK's. Some of the most promising molecules have been evaluated by *in vivo* studies in specific mouse models. The specific *in vitro* binding assays with EGFRs and VEGFRs are planned.



Gefitinib



022

JUNK FOOD AND CANCER

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ABSTRACT

Nowadays we observe that the lifestyle of people worldwide has undergone drastic change. This lifestyle change has brought positive change as well as negative aspect to living, not only in developed countries such as USA but also in developing countries like India, Africa. In fast going life people have adopted the fast food (junk food), which savour their tongue and are quickly available. Junk food such as burgers, pizzas, chips, noodles have replaced nutritious food. Due to sedentary lifestyle people lack physical exercise leads to complications such as, obesity, blood pressure and continuous over intake of such food having high calorific value ultimately can lead to fatal and life threatening disease such as 'CANCER' (gastro intestinal tract, stomach, colorectal, endometrial).

Many health-minded individuals understand that eating fried or overcooked foods is unhealthy due to the chemical transition of normally stable fats to trans fats that have been shown to dramatically increase heart attack risk. Researchers from the University of the Basque in Spain publishing in the journal FOOD CHEMISTRY are the first to discover compounds released from common cooking oils or the oils used to fry fast food, that significantly increase the risk of neurologic degenerative diseases and a variety of different cancers. Breakdown chemical structures known as aldehydes are formed in cooked vegetable oils such as sunflower oil when heated to normal frying temperatures, and are also released into the air where they can be inhaled. Alternate food preparation methods such as roasting, steaming and broiling are safe methods of cooking foods to avoid the dangerous release of aldehydes and provide a shield against cancer-forming particles and neurodegenerative decline.

As a pharmacist, we would like to suggest to avoid sedentary lifestyle to some extent and balance it with regular exercise, and include fibrous food which has low calorific value and are highly nutritious. The high calorie food adopted from the western cultures, which make our life actually a fat bin, should be replaced by Indian nutritious food, which can be the best possible anti – cancer step.

023

Brain cancer and molecular mechanism of anti-cancer drug temozolomide for treatment of malignant-glioma

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ABSTRACT

Brain cancer is a disease in which cancer cells (malignant) arise in the brain tissue. Tumors composed of cancer cells are called malignant tumors, and those composed of mainly noncancerous cells are called benign tumors. The most common primary brain tumors are usually named for the brain tissue type from which they originally developed. These are gliomas, meningiomas, pituitary adenomas, vestibular schwannomas, and primitive neuroectodermal tumors (medulloblastomas). Gliomas have several subtypes which include astrocytomas, oligodendrogliomas, ependymomas, and choroid plexus papillomas. Malignant gliomas (glioblastoma multiforme and anaplastic astrocytoma) occur more frequently than other types of primary central nervous system tumors. Even with aggressive treatment using surgery, radiation, and chemotherapy, median reported survival is less than 1 year. The chemotherapy drug used most often to treat brain tumors is temozolomide (Temodar), which is taken as a pill. Temozolomide, a new drug, has shown promise in treating malignant gliomas and other difficult-to-treat tumors. This article reviews the mechanisms of pharmacological and cytotoxic effects of temozolomide and shows the results of clinical trial for the same. Temozolomide, a derivative of imidazotetrazine second-generation alkylating agent, is the leading compound in a new class of chemotherapeutic agents that enter the cerebrospinal fluid and do not require hepatic metabolism for activation. It is a triazene analog of dacarbazine with antineoplastic activity. *In*

vitro, temozolomide has demonstrated schedule-dependent antitumor activity against highly resistant malignancies, including high-grade glioma. In clinical studies, temozolomide consistently demonstrates reproducible linear pharmacokinetics with approximately 100% bioavailability, noncumulative minimal myelosuppression that is rapidly reversible, and activity against a variety of solid tumors in both children and adults. Preclinical studies have evaluated the combination of temozolomide with other alkylating agents and inhibitors of the DNA repair protein alkylguanine alkyltransferase to overcome resistance to chemotherapy in malignant glioma and malignant metastatic melanoma. Predictable bioavailability and minimal toxicity make temozolomide a candidate for a wide range of clinical testing to evaluate the potential of combination treatments in different tumor types. This drug has been approved in U.S. & European Union for treatment of adult patients with refractory anaplastic astrocytoma and for treatment of glioblastoma multiforme showing progression or recurrence after standard therapy respectively.

024

Nanotechnology and Liver Cancer

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ABSTRACT

Nanotechnology may open a new door on the treatment of liver cancer Liver cancer is one of the killer disease and more than five hundred thousand people worldwide are diagnosed every year. The patients are diagnosed when the tumor has grown around the size of 5 centimeter, which is most aggressive stage and most of the people die within six month time.

Although there are several techniques now such as CT scan, MRI, ultrasound for detecting Hepatocellular carcinoma, however none of the technique is effective for early diagnosis and by the time the cancer is diagnosed, it is difficult to treat it.

They used molecular-sized bubbles filled with chemotherapy drugs to prevent cell growth and initiate cell death in test tubes and mice.

Researchers evaluated the use of molecular-sized bubbles filled with C6-ceramide, called cerasomes, as an anti-cancer agent. Ceramide is a lipid molecule naturally present in the cell's plasma membrane and controls cell functions, including cell aging, or senescence.

025

Community approaches to colorectal cancer screening in India

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ABSTRACT

Colorectal cancer is the most common type of gastrointestinal malignancy involving the colon, rectum and anal canal. It comprises of 90% of all malignant tumors of large intestine. It is the commonest form of visceral cancer next only to lung cancer. Worldwide there are nearly one million cases which are diagnosed each year. The incidence of colorectal cancer rises with age and is seen mostly at average age of 60 years. Colorectal cancer is most common in males and seen in the ratio 2:1 (males: females). Clinical symptoms in colorectal cancer appear after considerable time. Most commonly seen symptoms are bleeding, change in bowel habits, loss of appetite (anorexia), and loss of weight (cachexia), anemia and weakness. Colorectal cancer is mostly screened by colonoscopy; proctosigmoidoscopy with double contrast barium enema. The latest method of screening colorectal cancer is (FOBT) which is fecal occult blood test. Pharmacist can play important role in screening colorectal cancer. Various means are mail, non-mail (telephone, audiovisual, computer), and multiple component strategies. Characteristics of mail based interventions are multiple mail outs, pre-notifications and information booklets. Characteristics of non mail based interventions are telephone outreach, telephone education , printed materials, non medical documentary, group meeting with gastroenterologist , kit with explanatory flyer were given with request to return, automated telephone out reach with speech recognition, emphasizing importance of screening. Characteristics of multiple components interventions involve education or self-empowerment of cultural groups. As colorectal cancer is featuring among top cancers pharmacist can be of great importance throughout the screening approach. This approach should be implemented not only to screening but also in overall management of colorectal cancer.

026

Novel chemotherapeutics: an answer for treatment of metastatic and resistant breast cancer?

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ABSTRACT

Resistance to chemotherapy in breast cancer is a substantial issue in current clinical scenario, restraining the effectiveness of the treatment regimen. Resistance is responsible for treatment failure in more than 90% of clinical cases of metastatic breast cancer. Understanding the mechanisms involved in resistance and overcoming them is a crucial and challenging task for effective management of metastatic breast cancer. Moreover, success rate of multi-drug resistance (MDR) reversal is low as on now in patients. On the brighter side, few targeted therapies are well established in the clinic. In this review, we will discuss different mechanisms involved leading to breast cancer resistance and potential targeted therapeutic alternatives to deal with the issue. Insight of few class of compounds would also be highlighted which are under extensive research such as HER2 receptor inhibitors, Inhibitors of the PI3K/Akt/mTOR pathway, Src-family tyrosine kinases inhibitors, PARP inhibitors, HSP90 inhibitors. In addition, novel cytotoxics such as the epothilones, having low susceptibility to some of the common types of drug resistance and have demonstrated activity in taxane-resistant breast cancer, are promising. These therapies target specifically, bypassing the pathway involved in resistance and may turn out to be the alternative therapeutic options to treat resistant breast cancer. There is, therefore, some

sanguinity for the improvement in the management and survival of patients with metastatic breast cancer with or without resistance.

027

Detection of Circulating Tumor Cells by Surface Enhanced Raman Spectroscopy

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Vidhi Khanna, Tanvi Shah & Malhar Khakharia

ABSTRACT

Body fluids are easily accessible and are valuable for medical diagnosis. Intriguing tools found in the body fluids are tumor cells circulating in the peripheral blood of cancer patients, known as Circulating Tumor Cells (CTCs). CTCs are cells that have detached from a primary tumor and circulate in the bloodstream. As these cells are extremely rare, they constitute a challenge for clinical diagnostics. We study the Raman Spectroscopic-based identification of such cells in suspension that are found in peripheral blood of cancer patients. Since, low specificity, low sensitivity, and the time consuming nature of current approaches have impeded the clinical inferences of these cells, Raman Spectroscopy could be a valuable method for their detection. A modification of Raman spectroscopy, called Surface Enhanced Raman Spectroscopy (SERS), is used directly to measure targeted CTCs in the presence of white blood cells. SERS nanoparticles, like gold, with epidermal growth factor peptide as a targeting ligand, have successfully been used to identify CTCs using the suggested method. The detection and characterization of circulating tumor cells (CTC) holds great potential for personalizing medicine and optimizing systemic therapy, especially for metastases. This technique may provide an important new clinical tool for management of patients with Squamous Cell Carcinoma of head and neck, Lung Cancer, Breast Cancer, etc. and its prognosis.

028

Advances in cancer immunotherapy: role of interleukins

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ABSTRACT

The term ‘cancer’ encompasses a large number of diseases and involves unregulated cell growth. Healthy cells divide and grow uncontrollably and invade nearby parts of the body. The traditional options for management of cancer are surgery, chemotherapy, radiation therapy and palliative care. However these treatment modalities have their own drawbacks and have a low to moderate success rate.

Recently, immunotherapy has been explored as a technique for destruction of cancerous cells. The main premise is stimulating the patient’s immune system to attack the malignant tumor cells

and destroy them. Interleukins are potent regulatory proteins produced in minute quantities by immune cells that are capable of enhancing tumor cell recognition and destruction by the cytotoxic effector cells. These interleukins can be targeted in the vicinity of tumor cells by binding them to anti-tumor antibodies thus increasing the probability of hitting the target cell. A number of interleukins have undergone laboratory trials and have reached the clinical studies stage. This review helps us to understand how the use of cytokines has impacted options available for management of cancer. The latest research trends in cancer immunotherapy have been summarized for the benefit of the pharma student fraternity. Molecular mechanisms involving interleukins have also been elucidated.

029

Ovarian cancer

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ABSTRACT

With the highest prevalence in western countries and especially among the white population, ovarian cancer continues to be the disease with second highest mortality ratio. Currently, 1st-line chemotherapy consists of a combination of carboplatin and paclitaxel to which approximately 80% of women respond. Women with recurrent ovarian cancer can be treated with secondary cytoreduction followed by chemotherapy or by chemotherapy alone. Advances in survival will depend on development of more accurate screening techniques and the development of new paradigms in treatment. However, many questions still remain regarding what constitutes optimum chemotherapy in ovarian cancer.

A recent study has also demonstrated that chemotherapy with intraperitoneal cisplatin was superior to intravenous cisplatin in patients with optimal stage III ovarian cancer. However, additional confirmatory trials are needed to define the role of intraperitoneal therapy when combined with paclitaxel. In advanced disease, the standard of care in the United States is maximal surgical cytoreduction followed by paclitaxel/carboplatin chemotherapy. Results from the Gynecologic Oncology Group GOG 158 trial show that paclitaxel/carboplatin is at least as effective as paclitaxel/cisplatin and is better tolerated and easier to administer.

Results from the International Collaborative Ovarian Neoplasm ICON 4 trial indicate that paclitaxel/carboplatin may offer superior efficacy to single-agent carboplatin. Finally, a variety of new cytotoxic and biologic agents are being evaluated in recurrent disease, either as single agents or in combination with standard chemotherapy.

030

ROLE OF PHARMACIST IN CANCER MANAGEMENT

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ABSTRACT

Cancer known medically as a malignant neoplasm, is a broad group of various diseases, all involving unregulated cell growth. In cancer, cells divide and grow uncontrollably, forming malignant tumors and invade nearby parts of the body.

Many things are known to increase the risk of cancer, including tobacco use, certain infections, radiation, lack of physical activity, obesity and environmental pollutants.

PHARMACIST is a highly professional individual which involves in providing health care to patients and is mainly involved to PROLONG the life of cancer patients. Cancer patients in the due course suffers from severe unbearable pain. To overcome this, PHARMACOTHERAPY is said to be cornerstone of cancer pain management. This is done by optimizing medication therapy, education regarding drug use, pain & symptom control.

ONCOLOGY PHARMACIST is a licensed pharmacist with special training in how to design, give, moniter & change chemotherapy for cancer patients. A pharmacist plays a pivotal role in post-chemotherapy sessions by assisting in pain management

CANCER PHARMACIST GROUP (CPG) is an Austria based group serving cancer patients. It is comprised of pharmacist practicing in medical oncology, hematology, chemotherapy preparation services. The pharmacist meets with the patients who are starting new anticancer therapies to counsel them on administration and toxicities.

A pharmacist in near future in health systems have excellent opportunity to help provide supportive care to cancer patients.

031

Survivin: Novel Target for Cancer

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ABSTRACT

Survivin is a protein that inhibits apoptosis and regulates cell division. Surviving contain baculovirus inhibitor of apoptosis repeat protein domain that classifies it as a member of inhibitor of apoptosis protein family. It functions as key regulator of mitosis and programmed cell death. Initially, survivin was described as an inhibitor of caspase-9. Research studies have shown that the role of survivin in cancer pathogenesis is not limited to apoptosis inhibition but also involves the regulation of mitotic spindle checkpoint, promotion of angiogenesis and chemoresistance. Survivin is expressed in embryonic tissue as well as in majority of human cancers, but is not expressed in most normal adult tissues. The cancer specific expression of survivin coupled with its importance

in inhibiting cell death and in regulating cell division, makes it a useful diagnostic marker of cancer and a potential target for cancer treatment. The multiple functions of survivin and regulation of apoptosis, the promotion of tumorigenesis and development of surviving inhibitors as a novel anticancer therapeutic strategy.

032

Germany´s Rich Herbal Traditions

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ABSTRACT

Phytotherapy studies constituents and uses of medicinal properties of plants. Especially in Germany the use of herbal products is the most widespread among European countries. Today every nation turns to Germany for scientific information on herbs. Most of the best selling products in the United States of America are also from Germany.

The work reported in the poster will give you an overview about herbal medicines produced by German companies. In focus the poster will show Germany´s rich herbal traditions including a short view into the regulatory application for new herbal medicines in Germany and will also focus why Germany as a nation is leader in herbal medicines.

033

The emerging role of herbal medicine in health care in Europe

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ABSTRACT

Herbal medicine has a long tradition in Europe. After China, Central Europe has captured the best documentation on the early use of plants as herbal remedies. Today, almost 40% of all drugs listed in the German Physicians Desk Reference are derived from plant material. Fifty percent of the world sales of herbal remedies occur in Europe. It has the most developed market in the world in the area of phytomedicines with the best established criteria for licensing and quality control.

In many countries such as Germany, France, or Italy treatment with phytotherapeutics has become well established and is regulated by the federal authorities. The costs for the therapeutic use of many herbal drugs are even covered by health insurance plans. In other countries such as the United Kingdom and the Netherlands, phytotherapeutics are still classified as dietary supplements. Germany can be regarded as a model for other international development.

034

Myrtol - A herbal medicine in Cancer Treatment

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ABSTRACT

Myrtol is commonly known as *Myrtus communis*. It is an evergreen shrub or small tree, growing to 5 m tall. The leaf is entire, 3–5 cm long, with a fragrant essential oil. The plants growth mostly in moist forests. It is seen in the areas of the Mediterranean region, the canaries and the central Asia. The chemical composition of Myrtol is phenolic compounds. It has been shown to be infective in interment of bacterial, fungal infections, inflammation, diabetes and also in cancer treatment. This poster focuses on anticancer properties of Myrtol.

035

Palash – Focus on anti-fertility activity

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ABSTRACT

Fertility control is an issue of global and national public health concern. India will become the most populated country exceeding china. There are many classes and types of anti-fertility products available in market. Most of the products there is compliance issue from patients perspective and also have serious side effects after long term use.

Worldwide many herbal medicines are used as anti-fertility drugs. Palash (Butea monosperma) has been known to posess anti-fertility activity. Palash is commonly found in Indian Subcontinent and Southeast Asia. Its chemical constituents are Cajanin and isoformononetin; Stigmasterol; Butin; flavonoids, isobutrin and butrin

Other than anti-fertility Palash is also used in treatment of helmianthesis, convulsions, diabetes and liver diseases to mention a few. Clinical studies have proven its anticonceptive, antiesterogenic and antifertility activity.

Our poster mainly focuses on clinical studies of Butea monosperma.

036

Green Tea a day keeps diseases away

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ABSTRACT

Tea is the most consumed drink in the world after water. Green tea is a 'non-fermented' tea, and contains more catechins, than black tea or oolong tea. Catechins are *in vitro* and *in vivo* strong antioxidants. Green tea is made solely from the leaves of *Camellia sinensis* belonging to family Theaceae that have undergone minimal oxidation during processing. Green tea originates in China and has become associated with many cultures throughout Asia.

It contains polyphenols, flavonoids, and caffeine which increase the antioxidant potential of Green tea. Since ancient times, green tea has been considered by the traditional Chinese medicine as a healthful beverage. Recent human studies suggest that green tea may contribute to a reduction in the risk of cardiovascular disease and some forms of cancer, as well as to the promotion of oral health and other physiological functions such as anti-Alzheimer activity, anti-cancer, anti-hypertensive effect, body weight control, antibacterial and antiviral activity, anti-fibrotic properties, and neuro protective power. Although all the evidence from research on green tea is very promising, future studies are necessary to fully understand its contributions to human health,

and advise its regular consumption in Western diets, in which green tea consumption is nowadays limited and sporadic. The above studies clearly show the value of green tea as effective means of preventing various ailments.

037

THERAPEUTIC WONDER – WHEATGRASS

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ABSTRACT

Biological source of wheatgrass is *Triticum aestivum* (subspecies of the family Poaceae). Other common names for wheatgrass are couchgrass, wheatgrass diet, agropyron. Western wheatgrass grows in east of the Cascade Range from USA, Canada, South east Asia.

Wheatgrass is commonly used to treat a number of conditions including the common cold, coughs, bronchitis, fevers, infections, and inflammation of the mouth and throat. In folk medicine, practitioners used wheatgrass to treat cystitis, gout, rheumatic pain, chronic skin disorders, and constipation. Some proponents equate chlorophyll (the component that makes wheatgrass and other plants green) with hemoglobin, which carries oxygen in the blood, saying that wheatgrass raises the body's oxygen levels. It strengthens the immune system, kills harmful bacteria in the digestive system, and rids the body of toxins and waste matter. Wheat grass as an adjunct may be effective in quality of life improvement for the terminally ill cancer patient. Wheatgrass for improving blood and platelet count. It contains Vitamins A, B1, 2, 3, 5, 6, 8, and 12; C, E and K. A teaspoon of wheat grass contains around 15mg of Calcium, 8mcg Iodine, 3.5mcg Selenium, 870mcg Iron, 62mcg Zinc, and many other minerals. Various clinical studies have been conducted on wheatgrass which have shown its ophthalmological uses, blood rebuilding, detoxifying effects, use in infection and oral health, deodorizing properties, treatment of skin diseases and wound healing. This poster focuses on various therapeutic uses of Wheatgrass.

038

Velvet Bean Used in Treatment of Parkinsonism disorder

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ABSTRACT

Velvet bean is commonly known as velvet bean or cowitch, *Kiwanch, Khaajkuiri. It is the mature seed of plant Mucuna pruriens belong to the family of* Fabaceae. The plant found in tropical Africa,

India and the Caribbean. It has been mentioned in Ayurved in the treatment of parkinsonism and genitourinary disorder.

Velvet bean contains high concentrations of levodopa, a direct precursor of the neurotransmitter dopamine. It also contains serotonin (5-HT), 5-HTP, nicotine, N,N DMT (DMT), bufotenine, and 5-MeO-DMT. The seed is prophylactic against oligospermia and is useful in increasing sperm count, ovulation in female.

Clinical studies have proven Velvet seed's activity in Parkinsons disease and spermatorrhoea and other genitourinary diseases. This poster focuses on Clinical studies of Velvet seeds in Parkinsons Disease.

039

Pre-cinical study shows link between anxiety and cancer.

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ABSTRACT

Anxiety is a multisystem response to a perceived threat or danger. Anxiety reflects a combination of biochemical changes in the body, the patient's personal history and memory and the social situation.

A study by Stanford University School of Medicine found that anxiety prone mice develops more severe cancer then their calm counterparts.

In mice stress comes from striking a balance between exploring to find food and mates, and protecting themselves from danger. Anxiety was introduced in hairless mice by placing them on a raised, cross-shaped tracks, which has one walkway enclosed by walls and other open. Mice were also placed in a large box, half light box and in half dark box and the time was noted down. After anxiety evaluation, hairless mice were exposed to UV rays for 10 mins about, three times a week, for 10 weeks. Tumors were seen on mice after few months. These tumors were vulnerable to immune system attack. Through all mice eventually developed skin cancer but the anxious mice had more tumors and that were invasive forms of cancer.

Comparison of immune system of low and high anxiety mice shows that nervous mice had higher levels of immune suppressing cells. The levels of hormone corticosterone were also cranked up in anxious mice, suggesting that they have more sensitive stress sensors.

This study from Stanford University School of Medicine by Firdaus Dhabhar has demonstrated a link between anxiety, stress and cancer progression.

040

Biomarkers in cancer research and treatment: promises and challenges.

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ABSTRACT

Cancer is one of the leading causes of the death worldwide. A key challenge in cancer control and prevention is detection of the disease as early as possible, enabling effective interventions and therapies to contribute to reduction in mortality and morbidity. Biomarkers are important as molecular signposts of the physiological state of a cell at a specific time. Cancer biomarkers can be used for prognosis: to predict the natural source of a tumor, indicating whether the outcome of the patient is likely to be good or poor. Although there has been significant progress in the technical development of biomarkers, implementation of their use in human populations has progressed much more slowly. Biomarkers are needed to be developed to fill gaps in our ability to observe steps in the continuum from exposure to disease. The sensitivity, specificity, and variability of biomarkers need to be better characterized and they must be better validated as predictors of disease risk. This review focuses on the new hope to the scientists that biomarkers can improve cancer screening, detection and also the drug development process.

041

DESIGN AND EVALUATION OF DOCETAXEL LOADED NANOPARTICLES MODIFIED WITH HYALURONIC ACID

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ABSTRACT

The main objective of this research work was design, development and evaluation of Docetaxel loaded nanoparticles modified with Hyaluronic acid (HA-DTX-NP) with improved safety, efficacy and bioavailability as compared to conventional therapy.

Targeted delivery of drugs and therapeutics can significantly reduce drug toxicity and increase the therapeutic effect. The frequent overexpression of the hyaluronan receptors on many types of tumors opens new avenues for selective targeting to tumors expressing the HA receptors. Solvent evaporation method using high pressure homogenization technique was used to prepare docetaxel loaded nanoparticles. The developed DTX-NP's were further surface modified by conjugating Hyaluronic acid (HA) using 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide as a catalyst. HA conjugated docetaxel loaded nanoparticles were prepared successfully with the properties including the 241.1 nm size, 0.253 P.I, -19.6mV zeta potential and 81.5% entrapement efficiency. Higher stability was achieved in the lyophilized nanoparticles compared to that in the nanoparticle suspension. Furthermore, less hemolysis effect was observed in the Bare DTX-NPs

and HA-DTX-NPs than that in the DTX Sol. To investigate efficacy of nanoformulations, the *In-vitro* Antiproliferative assay was done on Murine mammary cancer cell lines 4T-1. Pharmacokinetics were evaluated in wistar rat after i.v. injection of docetaxel formulated in Tween 80, Bare DTX-NP and HA-DTX-NPs. HA-DTX-NP was found to be promising formulations with increased drug bioavailability and improved efficacy.

042

POSITRON EMISSION TOMOGRAPHY IN BRAIN CANCER

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PET scan is a diagnostic examination that involves the acquisition of physiologic images based on the detection of radiation from the emission of positrons**.** The greatest benefit of PET scanning is that different compounds can show blood flow and oxygen and glucose metabolism in the tissues of the working brain. These measurements reflect the amount of brain activity in the various regions of the brain and allow learning more about how the brain works. PET scans were superior to all other metabolic imaging methods in terms of resolution and speed of completion (as little as 30 seconds), when they first became available. The improved resolution permitted better study to be made as to the area of the brain activated by a particular task. The ability to examine the functions of the body through biochemistry, thus, it is capable of detecting the disease even before changes take place. Since it is also capable of studying metabolic processes in the body, PET can be used as a great alternative to biopsy as well as other exploratory surgeries. It is considered as an accurate tool because of its ability to determine benign and malignant tumours.

PET is also useful in diagnostic medicine. It can be efficient in detecting tumours as well as the exact locations where cancer has spread. It can also examine numerous brain abnormalities and evaluate blood flow. Apart from the diagnostic nature of this technology, it is also helpful in determining the patient's response to the treatments.

043

Newer techniques in cancer detection

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ABSTRACT

A persistent limitation to current and future anti-cancer therapies is an inability to deliver high levels of active agent throughout the entire target tumor tissue volume without adversely impacting normal tissues. Interstitial transport is compromised by the poor mobility of macromolecules and nanoscale structures.

An invitro system to quantify the facilitated transport of superparamagnetic (SPM) nanoparticles (NPs) through model extracellular matrix (ECM) in vitro. SPM NP motion was induced by an external magnetic field. 135 nm radius NPs with a polyethylene glycol (PEG) surface moved through the ECM with an average velocity of 1.5 mm h-1, a velocity suitable for some clinical applications.

Steric barriers such as collagen I sharply limit interstitial delivery of macromolecular and nanoparticle-based therapeutic agents. Collagenase-linked SPM NPs overcame these barriers and moved through ECM in vitro at 90 μm hr-1, a rate similar to invasive cells, under the influence of a magnetic field. Temporal decay of collagenase activity shifted from an exponential behavior in solution to a linear relationship when NP-attached.

NP platforms offer the opportunity to develop a unified synthesis method for formation of multifunctional agents. We have demonstrated a facile method of conjugating multiple enzyme species to a NP via sulfhydryl-maleimide reaction chemistry. Horseradish peroxidase, α-glucosidase, and collagenase were simultaneously conjugated to the 300 Da PEG surface of SPM NPs at 15:1, 127:1 and 103:1 functional enzyme:NP ratio, respectively. SATP addition of sulfhydryl groups to each enzyme was achieved without significant reduction in enzyme activity. Cross reactivity of enzymes between enzyme activity assay systems was negligible.

Multifunctional NPs mimic complex invasive biological processes found in metastatic invasion and immune cell interactions. Isolated study of sets of enzymes in an invasion experimental system may make an ideal screening tool for blocking pathogenic invasive processes, including cancer metastasis and abnormal angiogenesis. Dispersion of otherwise immobile macromolecular or nanoscale therapeutic structures can be achieved with the proteolytic SPM NP carriers.

044

EVOLUTION OF CANCER

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ABSTRACT

Cancer is a disease known to man since 1500 BC but the cure is far from near. It claimed about 7.6 million lives in the year 2008 according to the WHO. Deteriorating lifestyles and environmental factors further add to the victims' claimed by cancer every year. Scientists all over the world are striving with various methods to inhibit the rapid proliferation of these cells. To fight cancer it is imperative to peek into its evolutionary history. Observing with a Darwinian perspective the criteria for natural selection is heritable variation which affects natural selection. Cancer cells very well satisfy these criteria and do evolve. Cells in neoplasms compete for resources, such as oxygen and glucose, as well as space. Thus, a cell that is mutated has a competitive survival edge over other cells. Cancer therapies act as a form of artificial selection, killing sensitive cancer cells, but leaving behind resistant cells. Often the tumor will regrow from those resistant cells, the patient will relapse, and the therapy that had been previously used will no longer kill the cancer cells. This selection for resistance is similar to the repeatedly spraying crops with a pesticide and selecting

for resistant pests until the pesticide is no longer effective. Natural selection in cancer also explains clonally transmittable or contagious cancer which includes Devil facial tumor disease, Canine transmissible venereal tumor etc. The emergence of these transmissible cancers in the Tasmanian devil, dogs and Syrian hamster may also be an evolutonary adaptation belive many oncologists. The solution is creating environment unfavorable for natural selection of the cancer cells. This view challenges the traditional view that cancer is caused only by a single gene called oncogene. The solutions like using anoxic bacteria and oncolytic viruses against cancer have far reaching consequences.

Key words- Heritable variation, drug resistance, contagious cancer

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