Public

Biography

Pradeep Acharya holds a master's degree in Biostatistics from Manipal University in India and currently working as Associate Director – Statistical Programming at Ephicacy Lifescience Analytics Pvt Ltd., Bengaluru.

He has 17+ years of Clinical Industry experience working in both Pharmaceutical Companies and CROs and has wide range of expertise in Biostatistics as well as Clinical SAS programming in various Therapeutic areas such as Oncology, Cardio-Vascular and Metabolism, Dermatology, Vaccines etc.

Pradeep is very passionate about presenting statistics papers and presented in various conferences such as IASCT-CONSPIC, PHUSE US Connect and PharmaSUG US, PHUSE EU Connect. He had conducted multiple workshops on Statistics and Clinical SAS Programming in reputed Universities and Colleges.



Public



EPHICACY
ISO 9001 & 27001 CERTIFIED COMPANY

Integrated SAS and R Programming for Automated Disease Progression Memo

Track: Automation Tools, Platforms & Data Visualization
Presentation Number: AT017

Presenter: Pradeep Acharya

THE EPHICACY EFFECT
→ Leading Experts → Flexible Service → Actionable Data →

Public

Agenda

- Oncology & Progression
- Progression intimation timeframe
- Automation
- Case Study
- Progression criteria based on RECIST 1.1
- SAS & R Code for Progression identification & Automation
- Advantages
- Conclusion
- References

Public

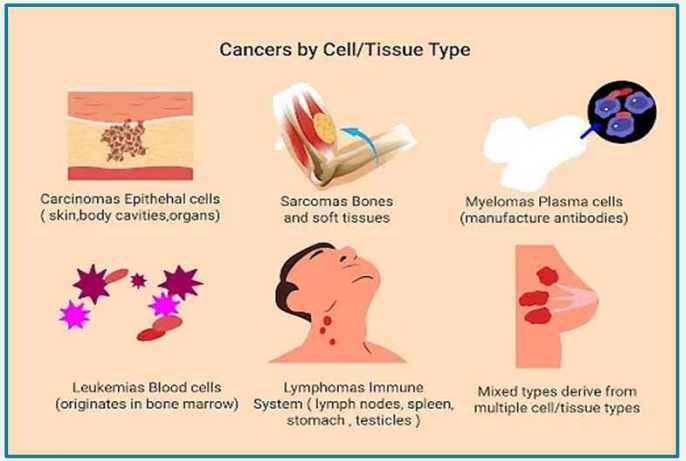
Oncology & Progression

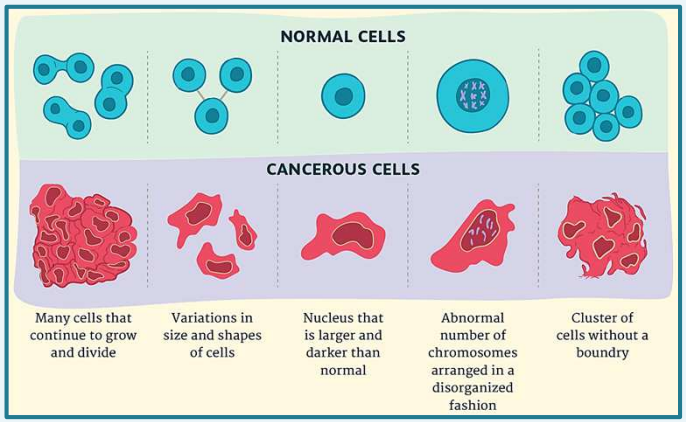
Oncology: The specialized branch of medicine dedicated to the study, diagnosis, treatment, and prevention of cancer

Cancer: A disease in which some of the body's cells grow abnormally, uncontrollably and spread to other parts of the body

- Broadly classified as *Solid Tumors* and *Liquid Tumors*

Disease Progression: The worsening of cancer characterized by tumor growth, the spread to new parts of the body, or the appearance of new lesions despite ongoing treatment





Public

Progression Intimation Timeframe

During an ongoing trial, raw data is typically transferred from electronic data capture (EDC) systems or external vendors (such as central labs or imaging centres) on a pre-scheduled cadence.

- Monthly data Transfer
- Quarterly data transfer
- Data transfer during dryruns
- Data transfers for planned interim analysis
- Data transfers for final DBL

Public

Automation

Automation is an activity using technology, machines, or software to perform tasks and processes with very little or no human interference

- Replaces repetitive manual work with automated systems.
- Uses sensors, computers, robots, or rules-based software.
- Controls physical machinery or digital data workflows

Used in various fields such as Manufacturing, Healthcare, Retail & Warehousing, Transportation, Office & Administration etc

Public

Automation in Healthcare

- Emphasizing in disease progression memo creation and notification to clinicians

- Can also be used for Treatment re-initiation memo

Public

Progression criteria based on RECIST 1.1

Baseline Study

Target lesions
- length diameter tumor ⩾10mm
- max 5, max 2 per organ
- short axis lymph node ⩾15mm
- Determine SLD sum of length diameters

Non-target lesions
- lesions <10mm
- non-measurable like pleural fluid, ascites, lymphangitis

Tumours	Malignant lymph nodes
CT scan: long axis ⩾ 10mm Chest X-ray: long axis ⩾ 20mm	*Short* axis diameter ⩾ 15mm





Selection of lesions

Choose 1 to 5 target lesions, equally distributed over affected organs (with a maximum of 2 per organ)

Preferably choose largest lesions

Preferably choose well-described lesions that are easy to measure

Table 1: Definitions of RECIST 1.1 Response Criteria

Response	Definition
Complete response	All lesions resolved; nodes must be <10 mm in short axis (normalized)
Partial response (PR)	>30% decrease in SOD of target lesions AND nontarget are non-PD
Progressive disease (PD)	≥20% increase in SOD AND ≥5 mm absolute increase from nadir OR new lesions
Stable disease	Neither PR nor PD

Note.—RECIST = Response Evaluation Criteria in Solid Tumors, SOD = sum of the diameters.

Public

Case Study

SUBJID	Visit	PSA	Nadir	% chg	abs chg
P001	1	4.2			
P001	2	4.5	4.2	7.1	0.3
P001	3	4.1	4.2	2.4	0.1
P001	4	8.9	4.1	117.1	4.8
P001	5	10	4.1	143.9	5.9
P001	6	9.9	4.1	141.5	5.8
P001	7	3.1	4.1	24.4	1
P001	8	7	3.1	125.8	3.9

SUBJID	Visit	PSA	Nadir	% chg	abs chg
P005	1	5.6			
P005	2	5.9	5.6	5.4	0.3
P005	3	12	5.6	116.1	6.5
P005	4	9	5.6	60.7	3.4
P005	5	3	5.6	46.4	2.6
P005	6	14	3	366.7	11
P005	7	15	3	400.0	12
P005	8	11	3	266.7	8
P005	9	7	3	133.3	4

SUBJID	Visit	PSA	Nadir	% chg	abs chg
P002	1	7.8			
P002	2	7.5	7.8	3.8	0.3
P002	3	7.2	7.5	4.0	0.3
P002	4	6.9	7.2	4.2	0.3
P002	5	6.7	6.9	2.9	0.2
P002	6	6.4	6.7	4.5	0.3
P002	7	8	6.4	25.0	1.6

SUBJID	Visit	PSA	Nadir	% chg	abs chg
P010	1	10			
P010	2	11	10.2	5.9	0.6
P010	3	11	10.2	3.9	0.4
P010	4	13	10.2	22.5	2.3
P010	5	14	10.2	34.3	3.5
P010	6	14	10.2	38.2	3.9
P010	7	15	10.2	45.1	4.6
P010	8	13	10.2	31.4	3.2
P010	9	9	10.2	11.8	1.2
P010	10	22	9	147.8	13.3

Note:

- SUBJID is Patient ID number
- Visit in Weeks
- PSA (ng/mL)
- Nadir is the lowest value from all the prior values
- % chg is the percentage change from Nadir
- Abs chg is Absolute change from Nadir

Public

SAS & R Code for Progression identification & Automation

```sas
 /* Create a pdf memo of subject with progression*/

ods pdf file="/path/to/your/file.pdf" new;

put
"_____________________________________________________________________________"
;
put "Dear Dr. &name.";
put "This memo is to notify you that, ";
put "The patient with ID number &sbjid. has disease progression as on visit
&vis.";
put "Current PSA Value is &currval. and the previous lowest value is
&nadir."
put "Please investigate and take necessary actions immediately.";
put
"_____________________________________________________________________________"
;

ods pdf close;



/* 1. Define the SMTP mail server options */
options emailsys=smtp emailhost="your-smtp-server-name" emailport=25;

/* 2. Set up the FILENAME statement with recipient and subject */
filename myemail email
    to="recipient@example.com"
    from="sender@example.com"
    subject="Disease Progression Memo of P001"
    attach="/path/to/your/file.pdf";
run;
```

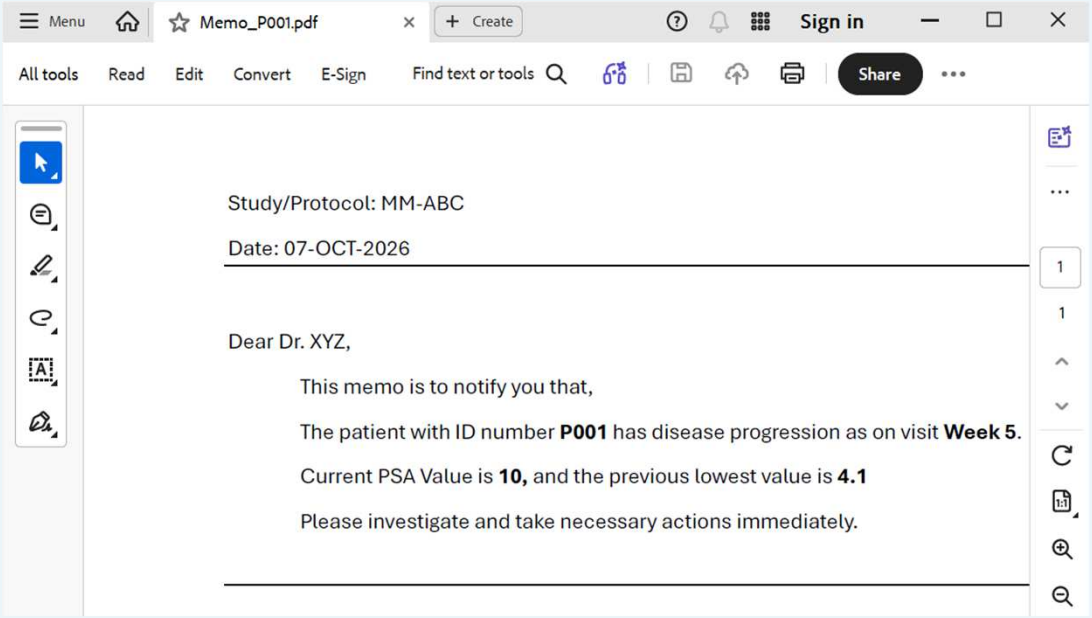
```
> email_body <- compose_email(
+     body = md("
+   Hello Dr. ABC,
+
+   This Memo is to notify you that the subject pt#1 has disease progression. Please investigate
 and take necessary actions ASAP.
+
+   Here are some bullet points:
+   - Current PSA value
+   - Previous lowest value
+
+   Best regards,
+   XYZ
+   ")
+ )
```

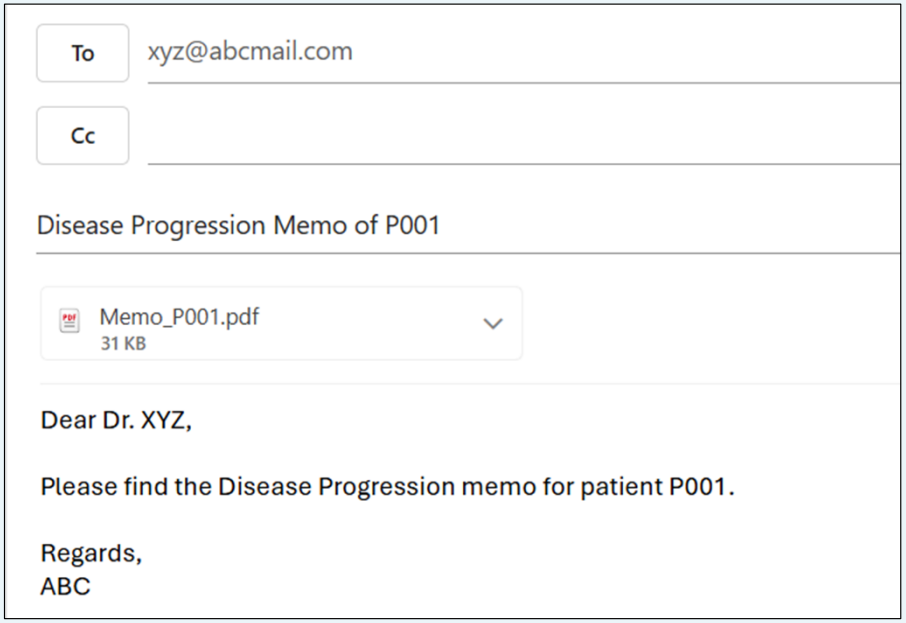


Progression_memo.sas

Public

Memo and email





Public

Advantages

- Memos are generated directly from raw dataset on a day-to-day basis
- As soon as subject(s) with disease progression identified, the memo will be sent to the clinicians for further investigation
- Provides clinicians with critical, real-time insights that directly improve patient outcomes and streamline hospital workflows
- No time delay. Hence patient gets timely response, better treatment and care

Public



Key Take Away Points

EPHICACY
ISO 9001 & 27001 CERTIFIED COMPANY

- Earlier Medical Interventions
- Reduction in Alarm Fatigue
- Minimized Human Error and Cognitive Load
- Enhanced Clinical Workflow Efficiency
- Standardized Care Protocols
- Optimized Resource Allocation


ANY
QUESTIONS
?


thank
you

Public



EPHICACY
ISO 9001 & 27001 CERTIFIED COMPANY

Name : Pradeep Acharya

Organization : Ephicacy Lifescience Analytics Pvt. Ltd.

Address : No. 6, 2nd Floor, 2nd Main, Arekere, Off Bannerghatta Main Road,

City, State ZIP : Bengaluru, Karnataka, 560076

Work Phone : +91 9986792197

E-mail : pradeep.acharya@ephicacy.com

Web : www.Ephicacy.com

Linkedin : https://www.linkedin.com/in/pradeepacharyabiostatistics/